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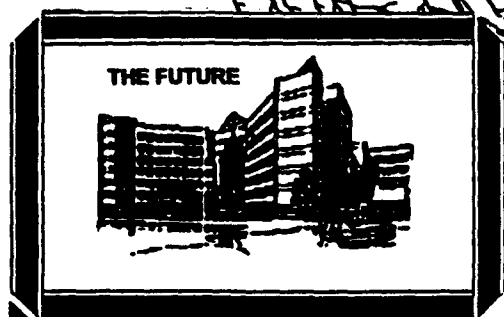


DEPARTMENT OF CLINICAL INVESTIGATION

ANNUAL RESEARCH PROGRESS REPORT

FISCAL YEAR 1992
VOLUME 1

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BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON, TEXAS 78234

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Distribution

FOREWORD

1992 was another productive year for the Brooke Army Medical Center (BAMC) Department of Clinical Investigation (DCI). The continuing productivity of the DCI is due to the support of the members of the DCI and from the Commander, BG Russ Zajtchuk; the Deputy Commander for Clinical Services, COL David A. McFarling; the Chief of Staff, COL Douglas A. Barton; and the training program chairmen.

The philosophy of the DCI is to support and encourage the academic pursuits of the housestaff and professional staff. The performance of quality research is only one aspect of this goal. Other aspects are to develop intellectual curiosity and the abilities to design clinical studies, analyze data, interpret results, explain the research efforts in written and oral form, and critically analyze scientific literature. The goal of the DCI is to assist in developing and fostering these research skills in academicians, scientists, and clinicians in the belief that clinical research promotes continuing medical education and ultimately benefits the patient. In keeping with this goal, Drs. Jean Johnson, John Ward, Earl Grant, and James Lamiell have continued to present their package of clinical research instruction to several clinical services.

Opening of the new BAMC animal research facility is scheduled to take place in July 1993. This is primarily the result of efforts by our previous veterinarian, LTC Denver Marlow and our present veterinarian, CPT Terri Clark. The new animal research facility will double our capability for supporting animal use protocols. This represents a substantial improvement since the number of animal use protocols continues to increase.

There has been a continuing increase in the acquisition of extramural funding to support the research endeavors of BAMC. The DCI serves as a resource and support service for investigators in obtaining these funds. Some DCI goals for 1993 include increasing efforts to obtain extramural funding and broaden the research teaching program to include a discussion of ethics in science and medicine.

This has been a fruitful year for the DCI. MAJ Grant and myself are indebted to the staff of the DCI and BAMC who have supported us during the past year. We are also grateful to those who preceded us and whose efforts made much of the progress of the past year possible. We look forward to another year of service to BAMC.



JAMES M. LAMIELL
Colonel, MC
Chief, Department of Clinical Investigation

COMMANDER'S AWARD WINNERS

First Place

Intubating Conditions with Mivacurium
Chloride: A Comparison of Neuromuscular
Blockade Monitoring at the Adductor Pollicis
and the Orbicularis Occuli

Samuel C. Sayson
Captain, MC
Anesthesiology & Operative Service
Department of Surgery

Second Place

Pharmacodynamic Doppler Determination of
Mitral Valve Area in Patients with
Significant Aortic Regurgitation

David M. Mego
Major, MC
Cardiology Service
Department of Medicine

Third Place

Capillary Refill Time in the Normal Newborn

Barton B. Cook
Captain, MC
Department of Pediatrics

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Statement A per telecon Helen Smith
Brook Army Medical Center HSHE-CI
Fort Sam Houston, TX 78234-6200

NWW 11/22/93

UNIT SUMMARY

- FISCAL YEAR 1992

A. Objectives

The objectives of the Department of Clinical Investigation are as follows:

1. To achieve continuous improvement in the quality of patient care.
2. To assist in the professional growth and development of the house staff by providing guidance and support in clinical research.
3. To provide a milieu conducive to retention of competent staff personnel and recruitment of new personnel.
4. To provide a review body for research proposals by investigators currently assigned to MEDDAC Units in an effort to promote an interest in Army medicine and retention in the Army Medical Corps.
5. To maintain an atmosphere of inquiry consistent with the dynamic nature of the health sciences.
6. To maintain a high professional standard and accreditation of advanced health programs.
7. To assure the highest level of professional standards in the conduct of human research and animal research.

B. Technical Approach

All research, investigational and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-7, AR 40-3, AR 70-25, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with the applicable regulations.

C. Staffing

<u>Name</u>	<u>Rank</u>	<u>MOS</u>	<u>Title</u>
Lamiell, James M.	COL	61F	Chief
Whiddon, Robert G., Jr.**	LTC	68A	Microbiologist
Marlow, Denver D.**	LTC	64B	Veterinary Lab Animal Office
Grant, Earl, Jr.	MAJ	68C	Biochemist
Yeager, Curtis*	CPT	68A	Microbiologist
Clark, Terri*	CPT	64B	Veterinary Lab Animal Officer
Jones, Sheila**	SFC	92B3R	NCOIC
Gueller, Glen E.	SFC	91C	Informatics Specialist
Hinds, Johnny W.**	SSG	92B3R	Med Lab Specialist
Duncan, Rory D.	SSG	92B3R	NCOIC
Irizarry, Zulma*	SGT	92B20	Med Lab Specialist
Guzman, Edwin*	SSG	92B30	Med Lab Specialist
White, James*	SPC	92B30	Med Lab Specialist
Harris, Ron**	SGT	92B20	Med Lab Specialist

C. Staffing (continued)

<u>Name</u>	<u>Rank</u>	<u>MOS</u>	<u>Title</u>
Cardona, Rene	SSG	91T30	Animal Care Specialist
Ruiz, Javier	SGT	91T20	Animal Care Specialist
Yoquelet, Curtis	SGT	91T20	Animal Care Specialist
Brand, Gary	PFC	91T10	Animal Care Specialist
Merrill, Gerald A.	GS11	00401	Research Immunologist
Ayala, Eleanor	GS11	00644	Medical Technologist
Grassel, Janice**	GS11	00404	Biological Lab Technician
Ward, John A.	GS13	00401	Research Physiologist
Johnson, Jean M.	GS12	00610	Research Nurse
Reeb, Barbara	GS11	00644	Medical Technologist
Davey, Inid	GS11	00644	Medical Technologist
Chapa, Isidoro	GS7	00645	Medical Technician
Williams, Dannie	GS7	00404	Biological Lab Technician
Rios, Roberto***	GS9	01020	Med Scientific Illustrator
Bratten, Dodie****	GS9	00301	Clin Research Protocol Coord
Smith, Helen J.*	GS7	00301	Clin Research Protocol Coord
Smith, Helen J.**	GS6	01087	Editorial Assistant
Corkill, Sarah*	GS5	19110	Secretary

* Assigned Jul 92, Jul 92, Jun 92, Sep 92, Sep 92, Apr 92, Jul 92, Jan 92

** Reassigned June 92, Aug 92, Feb 92, May 92, Aug 92, May 92, Jul 92

*** Assigned to IMD with duty in DCI

**** Expired Jan 92

Personnel:	Authorized	Required	Assigned
Officers -	4	9	4
Civilians -	11	16	10
Enlisted -	9	10	7

D. Funding

<u>Type</u>	<u>Fiscal Year 91</u>	<u>Fiscal Year 92</u>
Civilian personnel		
to include benefits	406,232.00	575,734.00
Consumable supplies	170,609.00	156,888.00
Civilian contracts		
to include consultants	13,852.00	14,689.00
TDY	4,500.00	13,817.00
Noninvestment equipment		
(Minor MEDCASE)	-----	655.00
Other OMA	-----	-----
OMA Total	291,339.00	761,784.00
MEDCASE	17,660.00	133,139.00
CEEP		55,575.00
Other (Bone Marrow Unit)		227,180.00
Military	539,126.00	661,545.00
TOTAL	1,563,926.00	1,839,223.00

Grants:

- a. U.S. Army Medical Research and Development Command - \$53,200.00
- b. Southwest Oncology Group - \$25,000.00

Protocol Disposition FY 92

	<u>Terminated</u>	<u>Transferred</u>	<u>Completed</u>	<u>Ongoing to FY 93</u>
FY 77	-		0	1
FY 85	1		0	1
FY 86	0		1	1
FY 87	0		2	5
FY 88	0	0	1	9
FY 89	4	0	1	20
FY 90	8		8	44
FY 91	4		11	72
FY 92	1			98
	18	0	23	251

Training Protocols

	<u>Terminated</u>	<u>Transferred</u>	<u>Completed</u>	<u>Ongoing to FY 92</u>
FY 86	0		0	3
FY 87	0		0	2
FY 89	1		0	0
FY 90	0		0	1
FY 92				4
	1		0	10

Oncology Group Protocols

SWOG	0		29	137
POG	0		9	72
GOG	0		1	46
			39	255

Number of resident and fellowship programs: 23
Number of residents and fellows with approved protocols: 106
Number of approved protocols held by this group: 96

Other training programs that use Clinical Investigation: University of Texas Health Science Center at San Antonio; University of Texas, Austin; Academy of Health Sciences Physical Therapy Branch.
Number of approved protocols held by this group: 18

Number of hospital staff members with approved protocols: 162
Number of approved protocols held by this group: 180

Drug evaluation/comparison studies: 100 (Does not include Oncology Group Protocols)

Significant Changes in the Last Year/Changes for the Future

The most significant change was obtaining final approval of the plans for a new temporary building to house small animals. Construction is due to start in early 1993.

We have become more proactive in recruiting investigators in the MEDCEN.

We are expanding our collaborative efforts with extramural sources. MRDC, the University of Texas Health Science Center at San Antonio and Austin, Cancer Therapy Research Center, and the State Chest Hospital are all collaborators.

Changes in Support of Growing Graduate Medical Education Requirements

We are aware of the growing requirement to have documented classroom hours devoted to research topics such as ethics, statistics, informed consent, protocol development, etc. These requirements are being met by going to the departments and offering tailored instruction for each unit's needs.

We are increasingly taking advantage of gifts and grants offered through the Jackson Foundation and organizations such as Facilitators of Applied Clinical Trials (FACT) and other not for profit organizations. These efforts are slowed by the requirements for lengthy approval chains for relatively small amounts, but progress is being made in the utilization of these resources.

Publications and Presentations Reported in 1992

Publications: 92
Abstracts: 27
Presentations: 14

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Brooke Army Medical Center
Fort Sam Houston, TX 78234-6200
DEPARTMENT OF CLINICAL INVESTIGATION

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Detail Summary Sheet

Date: ~ eb 93 Protocol Number: C-18-88 Status: Ongoing

Title: Development of an Indirect Chemiluminogenic Enzyme Linked Immunoassay (CELIA) for Demonstrating Conformational Changes in a Model Protein

Start date: 16 Dec 88	Estimated completion date:
Principal Investigator: Gerald A. Merrill	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s): Paul M. Horowitz, PhD, UTHSC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$4,690.00

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To develop monoclonal antibodies to rhodanese, a well characterized model protein, and use these antibodies in the development of an indirect soluble chemiluminescent enzyme linked assay system.

To assess the binding affinities of anti-rhodanese monoclonal antibodies for their epitomes and demonstrate conformational changes involving the rhodanese epitomes by monitoring changes in binding affinities.

Technical Approach: The study plan is to develop a series of antibodies to use in an attempt to better understand the structure-function relationships of a model protein, rhodanese (thiosulfate;cyanide sulfurtransferase). Knowledge of the relationships of between protein structure and protein functions will provide insight into the manipulation of proteins that have medical relevance, including hormones and enzymes. Such knowledge might then permit synthesis via genetic engineering of designer rescue proteins that could be used therapeutically.

Progress: Evaluation of the differences in conformation of bovine liver rhodanese as originally isolated from fresh liver and that of the recombinant form of the enzyme have been completed. The monoclonal antibody to the rhodanese epitope located in the first 73 amino acids of the enzyme sequence does not recognize the liganded or free form of the enzyme as isolated from bovine liver in active form. However, this antibody does bind to recombinant enzyme having the same specific activity as the isolated enzyme with an affinity constant determined to be $1.31 \pm 0.15 \times 10^6 \text{ M}^{-1}$. A second monoclonal antibody mapped to the same rhodanese fragment (1-73) did not bind to either the recombinant or the isolated enzyme, nor did a polyclonal site directed anti-rhodanese antibody whose epitope was mapped to residues 142-156 of the enzyme sequence. These results suggest a conformational difference between the enzyme conformers which is minor in magnitude. These differences may reflect difference in the histories of the

enzymes; including folding differences, differences in purification procedures, or differences in storage conditions-all of which could influence the final conformation of the enzyme. This result was published in reference 1.

A preliminary experiment indicated that each of the above antibodies could inhibit refolding of rhodanese to an active state. Prior to examination of this phenomenon, the study was refocused on the role of the amino terminus (distal portion of the sequence to which both of the monoclonal antibodies used in the above study recognize) in refolding of the denatured enzyme. This study involved limited enzymatic proteolysis of rhodanese with immobilized trypsin. The fragments obtained were separated by both size exclusion and ion exchange chromatography. The study concluded that when rhodanese was partially digested by use of immobilized trypsin, the digested enzyme retained greater than 50% of the original activity although less than 10% of the undigested enzyme remained. The predominant daughter species observed by polyacrylamide gel electrophoresis were two 31 kDa polypeptides whose amino termini corresponded to either residue 44 or 45 of the enzyme sequence. These 31 kDa fragments contained all residues required for the enzyme's sulfurtransferase chemistry. Following digestion, charged species were isolated by ion exchange high performance liquid chromatography. These enzyme variants were repeatedly washed and concentrated using a 10,000 molecular weight cut-off ultrafiltration membrane. Denaturing gel electrophoresis of these isolated enzyme variants revealed that a small peptide with a molecular weight of approximately 4 kDa remained associated with the 31 kDa fragment. This 4 kDa peptide appears to be the complementary fragment of the 31 kDa polypeptide, corresponding to the amino terminal 45 residues of the intact enzyme. Further proteolysis of the enzyme resulted in further cleavage yielding a 2.5 kDa peptide which could be dissociated from the enzyme under non-denaturing conditions with no apparent change in the migration of the 31 kDa fragment on SDS gels.

Undigested rhodanese, refolded after urea denaturation using three sets of refolding conditions, resulted in restoration of much of the rhodanese activity. Similar treatment of rhodanese subjected to prior limited tryptic digestion resulted in no regain of activity. Refolding of a mixture of intact and digested rhodanese resulted in regain of activity appropriate for the amount of intact rhodanese in the sample, indicating that the clipped rhodanese does not inhibit refolding of intact rhodanese.

It is concluded that portions of the amino terminus of rhodanese are important in the folding mechanism by which the amino terminus affects refolding could not be determined, potential roles for the amino terminus include portions which serve as nucleation centers for refolding, a role in prevention of misfolding of the enzyme, or a role in stabilization of conformers leading to active enzyme. These results are the basis for a manuscript presently in preparation.

Future studies will exploit the interference of the refolding effected by use of monoclonal antibodies and will examine the binding of antibodies to the newly produced human rhodanese clone and several bovine rhodanese forms produced by site-directed mutagenesis.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-1-90 Status: Terminated

Title: Development of Monoclonal Antibody from a 60-Kildodalton Oncofetal Tumor Marker found in Plasma of Cancer Patients.

Start date: 14 Nov 89	Estimated completion date:
Principal Investigator: Robert G. Whiddon, Jr., LTC, MS	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s): MAJ Donald E. Sutherland, MS
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): SW60 holds promise as a general tumor marker for nearly all types of cancer. A good source of SW60 will allow assay for the tumor marker by immunoassay, rather than by bioassay and the use of a laboratory rat. This study hopes to identify carcinoma cells grown in suspension culture as a good source of SW60.

Technical Approach: Following autologous bone marrow harvest and adjusting the hematocrit prior to freezer storage, excess plasma which is normally discarded will be forwarded to MAJ Sutherland at DDEAMC for use in the development of monoclonal antibody.

Progress: Associated investigator at Eisenhower has been diverted to dental protocols by his Medical Center. Plasma samples have been shipped to Eisenhower for assay. These are frozen and awaiting testing. We anticipate testing to recommence in the spring of 1992. Study closed due to transfer of principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-7-90 Status: Terminated

Title: Comparison of Noninvasive Venous Stop Flow CVP to Invasively Recorded Pressures

Start date: 7 Dec 90	Estimated completion date:
Principal Investigator: Ricky D. Latham, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service:	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objectives(s): The primary purpose of this proposal is to compare the venous stop flow (VSF) technique for measuring central venous pressure to the invasive technique using a high-fidelity catheter, which is currently the gold standard. Second, we will evaluate the accuracy of estimates of the zero level for fluid pressure reference. Finally, we will evaluate the physiologic effects of the VSF technique on cardiac chamber sizes, intracardiac pressures and IVC flow.

Technical Approach: During elective catheterization, the interjugular doppler velocity is recorded during forced exhalation to a specified pressure. The pressure levels are recorded in stepwise fashion. NASA-JSC investigators will read the data tapes blinded to actual CVP measurements. A comparison of noninvasive CVP will be made to invasive CVP recording.

Progress: I wish to terminate this study at this time since NASA JSC is unable to return the stop flow unit for completion of the study.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-16-90 Status: Ongoing

Title: Evaluation of Central Hemodynamics During the L1 Anti-G Straining Maneuver.

Start date: 18 Jan 90	Estimated completion date:
Principal Investigator: Ricky D. Latham, MAJ	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$50,340.00 (R&D)

Number of subjects enrolled during reporting period: 3
 Total number of subjects enrolled to date: 8
 Periodic review date: Review results:

Objective(s): 1) Evaluate left and right heart blood pressures and flows during two components of the standard L1 anti-G straining maneuver: an abdominal strain and peripheral muscle strain. 2) Measure SVC and IVC flows by noninvasive doppler to determine the effects as a function of time on venous return by this maneuver. 3) Evaluate blood pressure response by noninvasive means in the operational environment with and without straining.

Technical Approach: In part 1 of the study, 10 patients age 20-55 undergoing routine cardiac catheterization will be asked to perform several Valsalva maneuvers. At the same time blood pressure and flow velocity will be recorded. In part 2 of the Study, 10 healthy Army aviators, age 20-55, will be asked to wear a noninvasive portable blood pressure device to record blood pressures during flight in a high performance helicopter. An accelerometer will be used to record the g stresses encountered. A minimum of five flights will be used for the study.

Progress: No annual report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-4-91 Status: Ongoing

Title: Development of a Bioluminescent Assay of Extreme Sensitivity for Detection and Quantitation of Ricin

Start date: 16 Nov 90	Estimated completion date:
Principal Investigator: Gerald A. Merrill, PhD	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To develop a solid phase enzyme-linked sandwich assay of high sensitivity for the detection and quantitation of ricin which is based on avidin-biotin technology, enzymatic generation of ATP, and the sensitivity of photon counting detection of ATP via the bioluminescent luciferin-luciferase (firefly).

Technical Approach: A solid phase enzyme linked immunoassay for quantitation of ricin utilizes the chemiluminescence of a luminol derivative which emits light at alkaline pH following the removal of a phosphate group by the action and concentrate the toxin which may be present in very low concentrations. The quantitation of ricin that is immobilized involves addition of biotinylated anti-ricin followed by excess avidin-alkaline phosphatase which binds to biotin very tightly. The quantitation of the alkaline phosphatase can be either colorimetric or can be measured via luminescent methods with increased sensitivity using AMPPD as the substrate.

Progress: To permit rapid analysis of multiple samples, the assay was redesigned for assay in 96 well microtiter plates. The analysis portion of the assay must therefore be performed in a microtiter plate based luminometer. The research is performed in conjunction with USAMRIID, where such an instrument was available. Thus, progress on this project was limited to a 2-week reserve AT period at Ft. Detrick. During this time, the assay was redesigned to conform to the microtiter plate format and the sensitivity of the assay was evaluated. The assay was able to detect ricin at concentrations below 0.1 pg/ml. The assay was linear to approximately 25 pg/ml. The reproducibility of the assay was not determined, but it appears that daily dilutions of the stock solutions of ricin (10 mg/ml) to the very dilute concentrations measured was a source of considerable variation. Therefore, before the assay can be used quantitatively, a substock of ricin to be used for dilution must be established and its stability evaluated. In addition, a set of quality control standards must be established and the assay reproducibility evaluated. The recent acquisition of a microtiter plate based

C-4-91 (continued)

luminometer for the Department of Clinical Investigation will allow for continuation of the project at BAMC.

A modification of the assay involved substitution of the pyruvate kinase labeled avidin with alkaline phosphatase labeled avidin. This is the enzyme labeled component utilized in the original ELISA assay for ricin which is being refined. However, the p-nitrophenyl phosphate colorimetric substrate for alkaline phosphatase utilized in the ELISA was substituted with a luminol derivative (AMPPD). The action of alkaline phosphatase on AMPPD in an alkaline environment results in the generation of an excited luminol species which decomposes by photon emission. This sensitive chemiluminescent assay for detection of ricin was implemented. In a side-by-side evaluation of the sensitivity of this chemiluminescence assay and the ELISA assay for ricin, the chemiluminescent assay was 2-5 fold more sensitive, measuring ricin concentrations as low as 0.25 ng/ml. However, alkaline phosphatase is found in many bacteria, and slight contamination of reagents can lead to false positive reactions. For this reason a further modification of the assay is to be investigated in which a haloperoxidase is substituted for alkaline phosphatase and luminol derivatives are evaluated as potential substrates. The modifications will potentially create a sensitive and specific chemiluminescent assay for ricin.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-10-91 Status: Ongoing

Title: Correlation of Bone Marrow Biopsy Cellularity with Percentage of Nucleated cells Recovered from Autologous Bone Marrow Harvests

Start date: 30 Nov 90	Estimated completion date:
Principal Investigator: Barbara Reeb , MT (ASCP)	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: N/A

Number of subjects enrolled during reporting period: 28

Total number of subjects enrolled to date: 162

Periodic review date: _____ Review results: _____

Objective(s): To determine how well the nucleated cell count correlates with the percent cellularity at biopsy.

Technical Approach: This is a retrospective study to determine the relationship between the bone marrow biopsy cellularity reported and the percentage of nucleated cells recovered from the harvested marrow. Using this information it is hoped that a factor can be devised from the cellularity that can "correct" the nucleated cell count so a more accurate estimate of total cells and volume to be withdrawn can be achieved.

Progress: Collection of mid-harvest counts to calculate cells/kg at 500 mls of harvested marrows and cellularity of biopsies continues. The percent recovery of cells to date has been based on results from a semi-autotomed cell washer that recovers a buffy coat product. The average recovery has been 76.6± 14.0%. In early January '93, an automated instrument will be employed that will recover a mononuclear cell product. The effect of the cell counts and cellularity on recovery will be analyzed. Excess fat will be removed by an inverted spin, saline displacement or by inversion only.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-23-91 Status: Terminated

Title: The Mediating Effect of Temperament on Physiological Response to Immunization in Preschoolers (Relationship between temperament and cortisol response in 4-7 year olds undergoing a minor surgical procedure.)

Start date: 6 Feb 91	Estimated completion date:
Principal Investigator: Jean M. Johnson, PhD	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s): Gerald Merrill, PhD
Key Words: TEMPERAMENT CHILDREN STRESS	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$1,006.69

Number of subjects enrolled during reporting period: 3
Total number of subjects enrolled to date: 3
Periodic review date: Review results:

Objective(s): To explore the link between temperament and physiological responses to health care procedures.

TECHNICAL APPROACH: Pre- , post-immunization measures of salivary cortisol obtained in the home and in the pediatric clinic will be correlated with results of temperament questionnaire completed by parent.

PROGRESS: Inability to obtain sufficient volunteers resulted in redesign of the study to children having a day surgery procedure for pressure equalizing tube insertion/removal. Notification about the study could be sent to parents of children on the surgery schedule thus eliminating the need for reliance on general advertising for subjects. Procedures were modified slightly to fit this population. Only 1 subject was obtained during the 6 month phase of this study.

Study is terminated due to lack of subjects.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-25-91 Status: Ongoing

Title: Automated Screening of Western Blot Densitometry Scan for the Detection of Type-Specific Herpes Virus Antibodies.

Start date: 6 Feb 91 Estimated completion date: 6 Feb 93

Principal Investigator: John A. Ward, PhD Facility: Brooke Army Medical Center, Texas

Department/Service: Department of Clinical Investigation Associate Investigator(s): Julia K. Hilliard, PhD

Key Words:

Cumulative MEDCASE cost: Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): To determine if the application of digital signal processing techniques and correlation analysis (DSPCA) of Western blot analysis (WBA) densitometry scans can be used to distinguish B virus antibodies from herpes simplex antibodies in human sera.

Technical Approach: 1) Average 30 samples of WBAs to establish density pattern representative of both common and type specific antibodies for: a) HSV1 infected humans, b) HSV2 infected humans, and c) B Virus infected monkeys. 2) Subtract common antibody patterns from unknown WBAs to filter out the effect of cross-reacting antibodies. 3) Correlate type-specific patterns with filtered unknown WBAs and calculate correlation coefficients and standard errors. 4) Classify unknown WBAs on the basis of correlation analysis. 5) Tabulate successful and unsuccessful classifications of HSV1, HSV2, B virus and mixed infections and compare computer and human expert success rates using a contingency test.

Progress: Thirty reference scans representing infections with each type of virus (HSV1, HSV2, BV) were averaged to produce standard scans. When average standard densitometer scans were compared to a subset of the scans that were used to calculate the average, the correlation coefficient was a reliable means of classifying the type virus represented by the reference scan. The accuracy of classifying single virus infections did not always improve when comparison was made within type-specific band regions only instead of over the total densitometer scan. Preliminary studies of neural networks trained with the average standard scans indicates that they are a possible alternative to correlation analysis for classifying densitometer patterns. The accuracy of either method depends on how well the average standard or training set approximates the unknown samples the classification system will encounter. Both methods need to be tested against unknown mixed infections for comparison with the success rate of human experts.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-49-91 Status: Ongoing

Title: The Use of Polymerase Chain Reaction (PCR) to Detect Hepatitis C in Units of Donor Blood

Start date: 9 Apr 91	Estimated completion date:
Principal Investigator: Curtis L. Yeager, CPT, MS	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Of Clinical Investigation	Associate Investigator(s): William F. Nauscheutz, CPT, MS Victor Tryon, PhD
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To develop an assay to test for Hepatitis C virus (HCV) in units of donated blood collected at BAMC, using polymerase chain reaction and robotic technology.

Technical Approach: We intend to develop methods which combine the technology of robotics and high sensitivity and specificity of the polymerase chain reaction (PCR) to detect Hepatitis C virus (HCV) in approximately 300 units of donor blood daily. We will develop the system such that test results will be available the same day the units are drawn.

Progress: We are awaiting the arrival of equipment ordered. It is anticipated that lab work will begin in the early spring.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-58-91 Status: Ongoing

Title: Preparation of Large and Small Unilamellar Vesicles and Interaction with Magainin

Start date: 4 Jun 91	Estimated completion date:
Principal Investigator: Earl Grant, Jr., MAJ, MS	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To establish the means and verify the methodology that will produce well-defined liposomes for use as model membranes for the study of protein/peptide-lipid interactions and as potential drug carriers to aid in cancer therapy.

Technical Approach: Large unilamellar vesicles of various lipid compositions will be prepared by the reverse phase ether evaporation method. Small unilamellar vesicles of various lipid compositions will be prepared by sonication. The function integrity of the vesicles can be assessed by monitoring the release of entrapped 6-carboxyfluorescein in the absence and presence of Triton X-100.

Progress: Small unilamellar vesicles composed of Phosphatidylserine have been prepared by sonication. The functional integrity of these vesicles was confirmed by spectrofluorometric monitoring of the release of entrapped 6-carboxyfluorescein. Thus, we have established the means to produce small unilamellar vesicles.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-91-91 Status: Ongoing

Title: Molecular Detection of Bloodborne Pathogens in Blood for Transfusion with Emphasis on Hepatitis C.

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: Curtis L. Yeager, CPT, MS	Facility: Brooke Army Medical Center
Department/Service: Department of Clinical Investigation	Associate Investigator(s): William F. Nauscheutz, CPT, MS
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To develop methods which combine the speed and precision of robotics and the high sensitivity and specificity of gene amplification strategies to detect RNA from the hepatitis C virus in 300 units of volunteer donor blood daily.

Technical Approach: Research in this proposal is designed to adapt gene amplification techniques to a clinical diagnostic format capable of operating at a process level (300 plus tests per day). Research to be conducted includes identification and development of unique nucleic acid probes and primers, testing of amplification techniques, development of solid phase nucleic acid capture assays; adaptation of radiometric assays to machine-read fluorometric testing and side-by-side comparison of the molecular diagnostic assays developed versus the standard serological assay.

Progress: This study is pending approval of research funding by Medical Research and Development Command.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-59 Status: Terminated

Title: A Study of the Relationship Between Temperament and Salivary Cortisol Response in 4-7 Year Olds Undergoing a Minor Surgical Procedures.

Start date:	Estimated completion date:
Principal Investigator: Jean M. Johnson, Ph.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Clinical Investigation	Associate Investigator(s): Gerald Merrill, Ph.D.
Key Words: Temperament Children Stress	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$1006.69

Number of subjects enrolled during reporting period: 3
 Total number of subjects enrolled to date: 3
 Periodic review date: _____ Review results: _____

Objective(s): To explore the link between temperament and physiological responses to health care procedures.

Technical Approach: Pre-, post-immunization measures of salivary cortisol obtained in the home and in the pediatric clinic will be correlated with results of temperament questionnaire completed by parent.

Progress: Inability to obtain sufficient volunteers resulted in redesign of the study to children having an day surgery procedure for pressure equalizing tube insertion/removal. Notification about the study could be sent to parents of children on the surgery schedule thus eliminating the need for reliance on general advertising for subjects. Procedures were modified slightly to fit this population. Only 1 subject was obtained during the 6-month phase of this study. Study is terminated due to lack of subjects.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-105-90 Status: Ongoing

Title: Evaluation of Prophylactic Dicloxacillin in Cat Bite and Cat Scratch Wounds.

Start date:	Estimated completion date: Aug 93
Principal Investigator: Marc Daymude, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Emergency Medicine	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2
 Total number of subjects enrolled to date: 2
 Periodic review date: _____ Review results: _____

Objective(s): To determine if prophylactic treatment of cat bite and cat scratch wounds reduces the rate of infection.

Technical Approach: The study population will consist of 100 adult patients who have received cat bites within four hours of presenting to the Emergency Department. The study will use a randomized, double-blinded protocol to compare treatment with dicloxacillin to amoxicillin/clavulanate to placebo. All patients will be seen again 24-72 hours after initial presentation and will be called at home at the completion of the study. The percentages of infected wounds in the three groups will be compared using the chi-square test.

Progress: Two patients have been entered on the study.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-12 Status: Ongoing

Title: The Prevalence of Pneumococcal Vaccination among High Risk Patients Presenting to Military Emergency Departments

Start date:	Estimated completion date:
Principal Investigator: CPT Frederick Yates, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): 1) To assess vaccination prevalence in those high risk groups presenting at two major military Emergency Departments. 2) To address the utilization of the Emergency Department as part of a strategy for increasing adult immunization. 3) To compare the differences, if any, between military and a single civilian institution (already studied), and, 4) To compare pneumococcal vaccination prevalence differences, if any, between a major US Air Force and US Army Medical Center.

Technical Approach: Study proposed would consist of a single questionnaire. The question sheet will be distributed by the charge nurse to every patient entering the ED. Each care provider involved would be given guidelines on use of the pneumococcal vaccine. The decision to administer the vaccination would be based on 1) the patients' acceptance, 2) the patients medical condition as determined by the physician providing care in the Emergency Department at the time of presentation. Whether or not the vaccine was administered will be recorded and analyzed.

Progress: Data collection completed. Results to be published at a later date in SAEMS.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-32 Status: Ongoing

Title: The Use of Eye Patching in the Treatment of Corneal Abrasion

Start date:	Estimated completion date:
Principal Investigator: MAJ Henry E. Halloway, Jr., MC	Facility: Brooke Army Medical Center
Department/Service: Emergency Medicine	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): Proposed study is a multi-center randomized prospective evaluation of corneal epithelial defect healing, evaluating the use of double eye patching. This study will also compare discomfort and visual impairment with each of the two treatment plans.

Technical Approach: After appropriate history and ocular examination (visual fields, visual acuity, fluorescein staining, ophthalmoscopic and slit lamp) those patients with corneal epithelial defects and without any complicating lesion to any other parts of the eye will be asked to participate in the study.

Progress: No progress report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-60-86 Status: Ongoing

Title: The Natural History of HTLV-III Infection and Disease in a United States Military Population.

Start date: 25 Jun 86	Estimated completion date:
Principal Investigator: C. Kenneth McAllister, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Dept. of Medicine/Infectious Disease	Associate Investigator(s):
Key Words: HTLV-III	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 50
 Total number of subjects enrolled to date: 450
 Periodic review date: n/a Review results:

Objective(s): 1) To assess the impact of HTLV-III infection on fitness for duty (deployability, military readiness and retention) by systematically defining the natural disease progression in individuals with documented HTLV-III infections in the general military population (active duty, dependents and retirees).

2) To form an information basis and a study cohort upon which number other studies can be built (i.e., drug treatment of HTLV-III, etc.).

Technical Approach: Each HTLV-III infected individual will be staged according to the Walter Reed Staging Classification. The only additional requirements of individuals enrolled in this study are (1) additional information gathered from each individual as a consequence of this study will be centralized in a common data base; (2) serum and CSF will be stored at WRAIR for Future testing.

Progress: The study continues. Approximately 450 patients have been entered.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-2-87 Status: Terminated

Title: Percutaneous Transluminal Valvuloplasty in Adult Mitral/Aortic Stenosis.

Start date: 19 Nov 87	Estimated completion date:
Principal Investigator: Lawrence Pupa, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Cardiology	Associate Investigator(s):
Key Words: Stenosis, aortic Stenosis, mitral	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: 25 Feb 91 Review results: Continue

Objective(s): To apply the technique of percutaneous balloon dilatation of valvular aortic/mitral stenosis to a patient population at high risk of morbidity and mortality from aortic/mitral valve replacement and/or chronic anticoagulation.

Technical Approach: All patients age 21 or older with hemodynamically proven symptomatic aortic stenosis of either calcific/degenerative or congenital etiologies or patients age 21 or older with hemodynamically proven, significant mitral valve stenosis will be eligible if they are clinically considered to be high risk for surgical valve replacement or chronic anticoagulation. Cardiac catheterization and valvuloplasty will be performed as outlined in the study protocol.

Progress: Ten patients have been enrolled to date. Results are as follows: one patient - emergent valve replacement for mitral regurgitation; one patient required five unit transfusion for blood loss from groin hematoma; one patient death due to perforation; 7 patients - successes.

Protocol is not being pursued due to lack of current credentialed physicians in this procedure. Protocol has been terminated. No new findings to date.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-52-87 Status: Ongoing

Title: Autologous Bone Marrow Rescue in Patients with Acute Leukemia and Lymphoma Using Ex Vivo Marrow Treatment with 4-hydroxyperoxycyclophosphamide (4-HC).

Start date: 13 May 87	Estimated completion date:
Principal Investigator: Svetislava J, Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Oncology	Associate Investigator(s): Terry E. Pick, COL, MC Allen Potter, LTC, MC Barbara Reeb, DAC Robert G. Whiddon, Jr., LTC, MS
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4
 Total number of subjects enrolled to date: 6
 Periodic review date: 20 May 91 Review results: Continue

Objective(s): 1) To evaluate autologous marrow rescue after intensive therapy in patients with acute leukemia and lymphoma in second remission or subsequent remission or in early relapse.

2) To study the effects of ex vivo bone marrow purging utilizing 4-HC on malignant cells, marrow stem cells, and relationship to subsequent engraftment times.

3) To study the acute toxic effects of the preparative regimens.

Technical Approach: To be eligible for this study, all patients must have a diagnosis of acute leukemia or aggressive histology lymphoma and have relapsed after therapy. Bone marrow should be harvested when the patient is in remission.

Therapy will follow the schema outlined in the study protocol.

Progress: Four adults and two pediatric patients have been harvested over the past year and the marrow stored.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-62-87 Status: Ongoing

Title: Development of an Autologous Bone Marrow Rescue Program (Master Protocol).

Start date: 25 Jun 87	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Oncology	Associate Investigator(s): Terry E. Pick, COL, MC Allen Potter, LTC, MC Robert G. Whiddon, Jr, LTC, MS Barbara Reeb, DAC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$19,404.00

Number of subjects enrolled during reporting period: 39
Total number of subjects enrolled to date: 206
Periodic review date: _____ Review results: _____

Objective(s): 1) To develop an autologous bone marrow rescue program at Brooke Army Medical Center.

2) To participate in research and clinical studies individually as well as part of the Southwest Oncology Group and Pediatric Oncology Group.

3) To establish a competent marrow rescue service for all eligible DOD patients for present clinical indications and future indications, i.e., radiation exposure.

Technical Approach: Bone marrow stem cells will be obtained by multiple bone marrow aspirations under general anesthesia. The marrow will be prepared by accepted methods and frozen for future reinfusion. (This is the master protocol for the autologous bone marrow transplant program.

Progress: Since initial approval, 206 patients have been entered on this study. Approximately one-third of these patients have been treated with high dose chemotherapy with or without total body irradiation and bone marrow transplantation on various clinical studies. During the past year, 30 adults and 9 pediatric patients have been harvested. One patient sustained a urethral laceration during Foley placement but recovered without further surgery.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-64-87 Status: Ongoing

Title: Evaluation of Patients with Human Immunodeficiency Virus (HIV) Seropositivity Detected by Screening for the Presence and Potential Etiology of Exercise Intolerance.

Start date: 21 Jul 87	Estimated completion date:
Principal Investigator: James E. Johnson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Pulmonary	Associate Investigator(s): Gregg T. Anders, MAJ, MC Herman M. Blanton, MAJ, MC Eleanor Ayala, DAC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 48
Periodic review date: 19 Oct 92 Review results: Continue

Objective(s): Patients with HIV seropositivity have been noted to have exercise intolerance at an early stage when they are otherwise asymptomatic. The goals of this study are as follows: 1) To determine the prevalence of complaints of exercise intolerance and dyspnea in the study population. 2) To document whether abnormalities of exercise physiology exist in these patients complaining of exercise intolerance. 3) To evaluate these patients for potential causes of exercise intolerance such as early opportunistic pulmonary infection or lymphocytic interstitial pneumonitis (LIP).

Technical Approach: All active duty patients admitted to the HIV ward or referred to the HIV clinic for evaluation will be considered eligible for the study. These patients will be given a questionnaire on the day of admission including questions regarding exercise tolerance and dyspnea as well as previous lung, heart and muscle diseases. The response to these questions will be used for further patient selection. All participants will undergo gallium scan of the lungs, pulmonary function testing to include lung volumes and a $\dot{V}_{I\dot{C}O}$, cycle ergometry pulmonary exercise testing and bronchoalveolar lavage (BAL). The BAL fluid will be divided and submitted for the following: 1) staining for routine cytological evaluation (for evidence of viral infection) as well as for AFB and GM stains; 2) culture for AFB, Fungi, CMV and HIV virus; 3) HIV antigen testing for comparison to peripheral blood titers; 4) quantitation of lymphocytes, PMNs, monocytes as well as lymphocyte subsets particularly OKT4 and OKT8.

Progress: No new patients have been added during the review period. However, Dr. Anders has made preliminary plans to revive this protocol and plans are underway for further studies of BAL inflammatory cell cytokine production in conjunction with Dr. Cox's lab at San Antonio State Chest Hospital. infected patients at various stages has been published. Since publication of the paper, patient accrual has continued.

Cox, R.A., Anders, G.T., Capelli, P.J., et al. Production of Tumor Necrosis Factor-Alpha and Interleukin-1 by Alveolar Macrophages from HIV-1-Infected Persons. AIDS Research and Human Retroviruses, 6(4):431-441, 1990.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-11-88 Status: Ongoing

Title: Effect of Thyroid Replacement on Lipid Profile - Differences Associated with Keeping the TSH in Low Normal as Compared to Upper Normal Euthyroid Range.

Start date: 2 Dec 87	Estimated completion date:
Principal Investigator: Department of Medicine/Endocrinology	Facility: Brooke Army Medical Center, Texas
Department/Service: Albert M. Thomason, COL, MC	Associate Investigator(s):
Key Words: Euthyroid	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
 Total number of subjects enrolled to date: 3
 Periodic review date: 25 Feb 91 Review results: Continue

Objective(s): To demonstrate a difference in the lipid profile of euthyroid patients treated with higher or lower doses of thyroid replacement therapy.

Technical Approach: Patients being treated with thyroid replacement are enlisted as volunteers. Individual patients have their TSH levels adjusted by varying their thyroid replacement dose to above 3.5 mcIU or below 1.1 mcIU/ml depending on whether the initial value was above or below the mean euthyroid value of 2.3 mIU/ml. The patient is maintained at the lower or higher TSH value for 3 months as determined by monthly measurements. Then, the patient's serum lipid profile (cholesterol, triglyceride, and HDL cholesterol) is determined after a 14 hour fast x 2. Subsequently, the patient has his dosage of thyroid replacement adjusted to keep his TSH value in the opposite end of the euthyroid range from which it was initially. After three months of stabilization of the new value of TSH level, the plasma lipid profile is repeated. Subsequently, the patient again has his TSH value adjusted to a relatively higher or lower value depending on where he started initially. After another 3 month period of stabilization, lipid profile is obtained again.

Progress: No progress this past year because of lack of volunteers. A new effort will be made to recruit volunteers.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-19-88 Status: Ongoing

Title: Effect of Oral Agents vs Insulin Therapy on Lipid Profile.

Start date: 13 Jan 88	Estimated completion date:
Principal Investigator: Albert M. Thomason, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Endocrinology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
 Total number of subjects enrolled to date: 1
 Periodic review date: 19 Mar 91 Review results: Continue

Objective(s): To demonstrate whether low density lipoprotein cholesterol and total cholesterol-high density lipoprotein cholesterol ratios are worse in Type I diabetics treated with insulin as compared to oral agents.

Technical Approach: 30 patients being treated with oral hypoglycemic agents would be enlisted as volunteers. For the first 3 months, the patient would be followed on his/her usual oral hypoglycemic agent to determine average HGB A1C and lipid profile values. Subsequently the patient would be taken off the oral hypoglycemic agent and placed on human insulin therapy in such a dosage as to keep the Hgb A1C value as near as possible to the value the patient had while being treated with oral hypoglycemic agent. After 4 months on insulin therapy the patient's lipid profiles for the previous 3 months would be averaged to compare the lipid profile while on oral hypoglycemic therapy. Subsequently, the patient would be taken off insulin and restarted on the same dose of hypoglycemic agent as previously taken. At the end of 4 months, the patient's lipid profile would be averaged as before.

Progress: No progress this past year because of lack of volunteers. A new effort will be made to recruit volunteers (very difficult without being able to provide some kind of compensation).

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-88 Status: Terminated

Title: Domperidone (R 33,812) Compassionate Clearance Single Patient Protocol.

Start date: 22 Nov 88	Estimated completion date:
Principal Investigator: Eddie Starnes, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): John G. Carrougner. CPT, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: 2
 Periodic review date: 16 Sep 91 Review results: Continue

Objective(s): To treat patients with gastric stasis who have failed conventional forms of therapy.

Technical Approach: Only patients who have failed all other forms of therapy meeting the eligibility criteria may be entered on this study. Therapy will follow the schema outlined in the study protocol.

Progress: Study terminated. Principal investigator PCS'd from Brooke Army Medical Center.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-17-89 Status: Terminated

Title: Modification of Diet in Renal Disease Study.

Start date: 20 Dec 88	Estimated completion date:
Principal Investigator: Steven F. Gouge, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Nephrology	Associate Investigator(s): Dietary Staff, University of Texas Health Science Center, San Antonio
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
 Total number of subjects enrolled to date: 4
 Periodic review date: 16 Feb 93 Review results: Continue

Objective(s): To determine if one of two therapies can slow or prevent the development of end stage renal disease in patients with chronic renal disease: 1) a diet restricted in protein and phosphorus and/or 2) one of two levels of blood pressure control (mean arterial pressure less than 107 or less than 92).

Technical Approach: Participants will be assigned to an appropriate diet programs as determined by the dietary staff at the University of Texas Health Science Center and followed on a regular basis.

Progress: All BAMC patients enrolled in this large NIH-funded multicenter study have completed their portion of tghe study. However, they enrolled early and the study is ongoing. It will be several years before results are known. BAMC will have no forther contribution to the study and I suggested that this study be terminated by Clinical Investigation at this time.

Detail Summary Sheet

Date: 4 Feb 93
Ongoing

Protocol Number: C-23-89

Status:

Title: Retrospective Analysis of Acute Exacerbations of Chronic Renal Failure.

Start date: 27 Jan 89	Estimated completion date:
Principal Investigator: Steven F. Gouge, MAJ MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Nephrology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 212
Periodic review date: 3 Feb 93 Review results: _____

Objective(s): To determine the risk factors for, clinical presentations and outcomes of acute exacerbations of chronic renal failure; and to compare these variables in patients to patients with chronic renal failure without exacerbation and patients with acute renal failure without prior chronic renal failure.

Technical Approach: Records of patients with a discharge diagnosis of acute renal failure, CRF, or both during the period 1986 and 1987 will be reviewed.

Progress: We are awaiting repeat computer analysis of our data set. The associate investigator with this data and the ability to analyze has PCS'd to Madigan Army Medical Center (AMC) and has delayed working on this project until she has completed her Nephrology Subspecialty Board Examination. She is now the only nephrologist at Madigan AMC as the other nephrologist has been sent to JTF-Bravo for six months. Upon his return, she should analyze data set and thus we will have results.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-36-89 Status: Terminated

Title: A Prospective, Double Blind Study of Retrovir in Early HIV Infection.

Start date: 23 Feb 89	Estimated completion date:
Principal Investigator: J. William Kelly, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Dept. of Medicine/Infectious Disease	Associate Investigator(s): C. Kenneth McAllister, COL, MC
Key Words: HIV infection	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 2

Periodic review date: 20 May 91 Review results: Continue follow-up

Objective(s): To evaluate the safety and tolerance of chronic administration of Retrovir in adult patients with early manifestations of ARC, including those presenting with only HIV-associated lymphadenopathy and a CD4 cell count < 500 cells/mm³, and to assess the efficacy of Retrovir therapy in the treatment of HIV disease in these patients.

Technical Approach: This will be a placebo-controlled, double-blind study to evaluate the effect of 800 mg/day of oral Retrovir on the clinical, immunologic and virologic manifestations of early AIDS-Related Complex. Patients entering this trial will have signs and symptoms consistent with early stages of the disease and CD4 cell number < 500 but > 200 cells/mm³. The safety and tolerance of retrovir in this population will also be evaluated. Patients will be randomized to receive either Retrovir or placebo capsules for 96 weeks. Study medicines will be administered at a dose of 200 mg every 6 hours.

Progress: Study has been terminated in order to make patients available for other interventional trials.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-63-89 Status: Ongoing

Title: What is the Value of Fecal Hemoccult Blood Tests Performed at the Time of Digital Rectal Examination?

Start date: 26 Apr 89	Estimated completion date:
Principal Investigator: Shailesh Kadakia, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Eddie Starnes, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$750.00

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: 37
 Periodic review date: 20 May 91 Review results: Continue

Objective(s): To determine the clinical meaning and usefulness of positive fecal occult blood tests (Hemoccult Method) discovered at the time of routine digital rectal examination.

Technical Approach: Adult patients over the age of 40 with positive hemoccult tests obtained on normal appearing stool obtained at rectal examination will be eligible. All patients will be offered the standard of care which includes full evaluation of the lower GI tract (colonoscopy or flexible sigmoidoscopy/air contrast barium enema) and possibly the upper GI tract. Stool Hemoccult II samples will be collected on three consecutive days in the usual manner. Hemoquant assays will be obtained on the same spontaneously passed stool specimens used for Hemoccult II testing.

Progress: Over the last 12 months, 7 patients have been enrolled at BAMC and 20 patients have been enrolled at Tripler Army Medical Center where the protocol was also approved by the Clinical Investigation in IRB. The patients at Tripler are enrolled in the study by Dr. Charles Cohan, Major, Medical Corps, USA. A total of 64 patients have been enrolled to date, since the beginning of the study. The data has not been completely analyzed as of this date, however, significant findings are as follows: Three patients with carcinomas have been discovered. There appears to be a trend in favor of doing hemoccults at home using three hemoccult cards and hemoquants at home using the hemoquant kits and submitting the samples to the GI Clinic.

There appears to be no significant advantage of hemoquant over hemoccults in detecting the true positive cases. There appears to be no significant pathology found at colonoscopy or upper endoscopy in patients who do not have evidence of blood on three hemoccult cards. It appears that there is a trend in finding pathology in patients who show presents of blood during subsequent testing using the hemoccults or hemoquant.

There was one patient who had colitis after a colonoscopy the full report and followup of this patient was submitted to the Clinical Investigation Department for their review. There seems to be no need for revision of the C-

C-63-89 (continued)

protocol and we intend to continue the study as has been outlined in the past. Our final report will be provided as soon as the data is analyzed in its final form which we expect to end in the next four to six months.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-70-89 Status: Terminated

Title: Rifampin for Infusion (Compassionate Use Protocol).

Start date: 15 May 89	Estimated completion date:
Principal Investigator: J. William Kelly, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Dept. of Medicine/Infectious Disease	Associate Investigator(s): C. Kenneth McAllister, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
 Total number of subjects enrolled to date: 1
 Periodic review date: 14 Aug 91 Review results: Continue

Objective(s): To provide intravenous rifampin for "humanitarian" use in specific cases.

Technical Approach: Any patient satisfying one or more of the following criteria will be considered eligible for treatment with rifampin IV: 1) active tuberculosis where the drug cannot be taken by mouth, patients who do not tolerate oral medication, and in comatose patients (tuberculous meningitis); 2) infections with microorganisms resistant to approved antibiotics; (3) in patients with in vitro sensitivity tests positive to an approved antibiotic but who develop an allergy or exhibit an adverse reaction to that antibiotic, or whose disease is serious enough to warrant treatment with an investigational drug. Lyophilized rifampin will be reconstituted and administered according to established procedures.

Progress: One patient was enrolled but never received the medication. The drug has become commercially available.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-103-89 Status: Ongoing

Title: Single Patient Protocol for Treatment of Systemic Mycoses with Itraconazole (R51,211).

Start date: 2 Aug 89	Estimated completion date:
Principal Investigator: J. William Kelly, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Dept. of Medicine/Infectious Disease	Associate Investigator(s): C. Kenneth McAllister, COL. MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
 Total number of subjects enrolled to date: 1
 Periodic review date: 16 Sep 91 Review results: Continue

Objective(s): Compassionate use of drug Itraconazole for treatment of systemic mycoses.

Technical Approach: Eligible patients must have positive culture and/or histologic findings which identify the pathogen. Dosage will be initiated on 100 mg qd with a meal and maintained on that dose for at least a month. If patient is unchanged or worsening, dose may be increased in 100 mg increments to a maximum of 400 mg/day. The optimal duration of treatment is unknown, but a treatment course of about one year is planned.

Progress: No annual report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-107-89 Status: Ongoing

Title: Phase I Trial of Intrapleurally Administered Alpha Interferon in Malignant Pleural Effusions.

Start date: 14 Aug 89	Estimated completion date:
Principal Investigator: Howard A. Burris, III, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Oncology	Associate Investigator(s): Timothy J. O'Rourke, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 7
 Total number of subjects enrolled to date: 9 BAMC; 6 UTHSCSA
 Periodic review date: thru 31 Dec 92 Review results: Continue

Objective(s): 1) To determine the tolerance to and toxicity of intrapleural administration of Intron-A in patients with malignant pleural effusions.

2) To determine antitumor activity of Intron-A intrapleurally as evidenced by control of pleural effusions.

Technical Approach: Treatment of eligible patients will follow the schema outlined in the study protocol.

Progress: Accrual has increased on this protocol with 7 patients entered last year (total of 15 patients enrolled; 9 from BAMC). No toxicity has been noted. The study continues to enroll patients.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-122-89 Status: Ongoing

Title: A Technique for the Growth of Epidermal Sheets Obtained from Patients Undergoing Reduction Mammoplasty.

Start date: 31 Oct 89	Estimated completion date:
Principal Investigator Jerome C. Hill, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Dermatology	Associate Investigator(s): Ronald E. Grimwood, LTC, MC, USAF Larry E. Becker, COL, MC William K. Becker, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$31,500.00 (R&D)

Number of subjects enrolled during reporting period: 2
 Total number of subjects enrolled to date: 2
 Periodic review date: 10 Sep 90 Review results: Continue

Objective(s): To establish a technique for isolating and growing epidermal sheets from cells obtained from patients undergoing reduction mammoplasty.

Technical Approach: Discarded skin was obtained from patients undergoing reduction mammoplasty. The epidermis was enzymatically separated from the dermis. Keratinocytes were isolated from the epidermis and seeded in 25 cm² cell culture flasks. The growth medium was Keratinocyte Growth Medium (KGM) which has been developed for the growth of keratinocytes. In approximately two weeks, the primary keratinocyte cultures were nearly confluent and were serially subcultured to expand the volume of cells.

When secondary cultures reached confluence, the cell medium was changed to Dulbecco's Modified Eagles' Medium containing 10% fetal calf serum. The change to a medium containing serum and a higher calcium concentration induced the keratinocytes to stratify into multi-layered sheets. These epidermal sheets were removed from the culture flask with Dispase, a neutral protease, and attached to petrolatum gauze. At this point the sheets could be used as skin grafts.

Progress: No annual report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-3-90 Status: Ongoing

Title: Differences in Response to Thiazide-Induced Hyponatremia by Gender.

Start date: 7 Dec 89	Estimated completion date:
Principal Investigator: Robert Oglesby, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Nephrology	Associate Investigator(s): Steven F. Gouge, MAJ, MC
Key Words:	
Cumulative MEDCASE cost: \$4800	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 7

Total number of subjects enrolled to date: 9

Periodic review date: n/a Review results: _____

Objective(s): To investigate the differences in response to water challenge testing by sex before and after administration of hydrochlorothiazide in a controlled, prospective fashion. This is to determine if recommendations for changing dosages or even changing drug therapy in the initiation of diuretic therapy is necessary for a wide range of outpatients in the U.S.

Technical Approach: Ten men and ten women, age 55 and above, with no concurrent hypertension or diabetes will be studied. Baseline blood tests will be drawn for serum sodium and potassium as well as thyroid function tests and serum cortisol levels. If these are normal, the patients will undergo a baseline water challenge test in which they drink 20 ml/kg of ideal body weight of fresh water followed by hourly urine samples for urine electrolytes and osmolality. Before the water load and after four hours, blood samples will be drawn for serum sodium, potassium, antidiuretic hormone, prolactin, and possibly diuretic levels and atrial natriuretic factor.

Progress: Study is ongoing.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-4-90 Status: Completed

Title: Utilization of Acute Bronchodilator Responses in Chronic Obstructive Pulmonary Disease to Predict Relative Efficacy of Individual Agents.

Start date: 7 Dec 89	Estimated completion date:
Principal Investigator: Mark D. Peacock, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Dept. of Medicine/Pulmonary Disease	Associate Investigator(s): James E. Johnson, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 22
 Total number of subjects enrolled to date: 22
 Periodic review date: 25 Feb 91 Review results: Continue

Objective(s): The objective of this study is to determine if testing the acute bronchodilator response of stable patients with chronic obstructive pulmonary disease (COPD) utilizing a panel of inhaled agents can correctly predict which agent will be most efficacious in improving the patient's exercise tolerance, dyspnea, and pulmonary function tests.

Technical Approach: Thirty patients with stable COPD will be recruited. After collection of baseline demographic data, each patient will complete a dyspnea questionnaire, perform a 12-minute walking test, and undergo a series of spirometries. Pulmonary function tests will be performed before and after administration of 4 or 5 different inhaled medications on 5 consecutive days.

Progress: Twenty-two patients were studied with no adverse reactions. We found that chronic therapy with the agent producing the best response acutely resulted in better pre- and post-dilator spirometry values ($p < .05$). The other parameters improved but were not statistically significant. Manuscript has been published.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-10-90 Status: Terminated

Title: Hemodynamic Tolerance to Hemodialysis in Critically Ill Patients: Prospective Comparison of Sorbsystem Bicarbonate Hemodialysis and Single-Pass Bicarbonate Hemodialysis.

Start date: 7 Dec 89	Estimated completion date:
Principal Investigator: Ronald Salmond, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Nephrology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: 25 Feb 91 Review results: Continue

Objective(s): This randomized prospective study is designed to compare hemodynamic tolerance to sorbent system-bicarbonate hemodialysis (SS-B), and single pass-bicarbonate hemodialysis (SP-B) in critically ill patients with acute renal failure (ARF) and examine the condition of arterial and mixed venous blood gas during SS-B and SP-B.

Technical Approach: Patients will be randomized utilizing a random number table into being dialyzed on four consecutive dialyses with alternating sorbent system bicarbonate and single pass bicarbonate dialysates. Body weight will be monitored continuously by use of electronic bed scale. Intravascular volume expansion with 0.9% saline will be used to maintain a systolic arterial pressure of at least 100 mm Hg during hemodialysis.

Progress: Project was terminated in June 1992, when Principal Investigator left the Army. No patients were ever entered.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-21-90 Status: Ongoing

Title: A Double Blind Clinical Evaluation of the Safety and Efficacy of Fenticonazole Cream (2% Fenticonazole Nitrate) in treatment of Tinea Pedis.

Start date: 25 Jan 90	Estimated completion date:
Principal Investigator: Larry E. Becker, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Dermatology	Associate Investigator(s): Richard A. Keller, MD
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 40
 Total number of subjects enrolled to date: 40
 Periodic review date: _____ Review results: _____

Objective(s): To determine the safety and efficacy of Fenticonazole Cream in the treatment of tinea pedis.

Technical Approach: Approximately 40 patients will be selected for participation in this study. Male and female patients eighteen years of age and older with clinical signs of moderate to severe tinea pedis will be treated for four weeks once daily with vehicle controlled placebo or active agent. Follow-up visits at 2 and 4 weeks and again at 6 weeks (2 weeks after completing treatment) will be used to evaluate clinical and laboratory evidence of success of therapy.

Progress: No annual report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-22-90 Status: Ongoing

Title: Phase II Clinical Trial of Anagrelide in Thrombocytosis of Myeloproliferative Disorders (70014), Compassionate Use.

Start date: 25 Jan 90	Estimated completion date:
Principal Investigator: Terry R. Jenkins, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
 Total number of subjects enrolled to date: 3
 Periodic review date: 20 May 91 Review results: Continue

Objective(s): To determine the ability of anagrelide to effectively reduce platelet numbers in patients with thrombocythemia, to determine the dose of anagrelide which would be required to reduce platelet numbers and the dose needed to maintain them at or close to normal levels and to evaluate the safety of this compound.

Technical Approach: Three patients have been enrolled on this study. Therapy is in accordance with the study protocol.

Progress: No annual report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-24-90 Status: Ongoing

Title: Induction of TNFa and IL-1 in Human Tuberculosis.

Start date: 5 Feb 90	Estimated completion date:
Principal Investigator: Gregg T. Anders, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Pulmonary Disease	Associate Investigator(s): J. William Kelly, MAJ, MC C. Kenneth McAllister, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$18,300.00 (R&D)

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: 20 May 91 Review results: Continue

Objective(s): The objective of this study is to determine the extent of tumor necrosis factor-alpha (TNF-a) and interleukin-1 (IL-1) production association with human tuberculosis. Peripheral blood monocytes cells (PBMC) from patients with positive purified protein derivative (ppd) skin reactions or active tuberculosis will be compared with healthy controls (PPD negative) by in vitro stimulation with mycobacterial antigens and killed Mycobacterium tuberculosis and the concurrent production of TNF-a and IL-1 measured by ELISA.

Technical Approach: Patients and healthy controls (staff volunteers) will be phlebotomized approximately 50 ml of blood by peripheral venipuncture. In vitro antigen stimulation of PBMC and measurement of TNF-a and IL-1 production by ELISA will be performed.

Progress: No annual report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-29-90 Status: Ongoing

Title: Epsilon-aminocaproic Acid Mouthwash Therapy For Dental Extraction of Lower Molar Teeth in Normal Subjects: A Double Blind Controlled Trial.

Start date: 13 Feb 90	Estimated completion date:
Principal Investigator: William Nickel, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/General Medicine	Associate Investigator(s): Williams P. Mills, Jr., LTC, DC Andrew A. Vorana, LTC, DC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 112
Total number of subjects enrolled to date: 237
Periodic review date: 20 May 91 Review results: Continue

Objective(s): To conduct a randomized, double blind placebo controlled trial to evaluate the effect of low-dose EACA as a mouthwash on the incidence of dry socket in the general population.

Technical Approach: Patients will be randomized to receive either EACA solution placebo (the same solution without EACA). This solution will be used to wash the extraction site and soak the dressing placed at the end of the procedure. A supply of the solution will be given along with instructions to use two tablespoons to swish in the mouth for 2 minutes. This will be done 6 hours after the procedure and then three times a day for 4 days. Three days and seven days after the procedure, the participant will be contacted to determine if there is any pain, how well they are able to eat, and any other problems the ma be having. If there is any indication of dry socket they will be asked to return.

Progress: No annual report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-40-90 Status: Ongoing

Title: Prostaglandin Excretion of Radiocontrast Induced Acute Renal Failure.

Start date: 12 Mar 90	Estimated completion date:
Principal Investigator: William G. Wortham, MAJ	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Nephrology	Associate Investigator(s): Steve Gouge, LTC, MC Janice Grassel, M. T.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1

Total number of subjects enrolled to date: 1

Periodic review date: 3 Feb 93 Review results: Continue

Objective(s): To determine if prostaglandins are diminished in response to radiocontrast administration in the human subject. Further to determine if the decrement, if noted, correlates with a change in renovascular resistance, renal blood flow and/or creatinine clearance during the acute period surrounding radiocontrast administration.

Technical Approach: Participants will be admitted 24 hours prior to cardiac catheterization for collection of a 24-hour urine sample for sodium and prostaglandin metabolites, thromboxane B2 and 24-hour creatinine. In addition, they will undergo a nuclear determination via plasma clearance, I¹³¹ Hippuran and DTPA to determine renal blood flow as well as GFR via radionuclide study 4-6 hours prior to catheterization, they will receive half-normal saline at approximately 125 cc/hour if not contraindicated by volume status. At cardiac catheterization, a determination of central venous pressure will be necessary. Immediately after contrast administration, a second spot renin and catechol determination will be made. After cardiac catheterization a 24-hour urine will be collected for prostaglandin metabolites and sodium and creatinine as well as routine serum creatinine and electrolytes. An I¹³¹ Hippuran and DTPA for determination of renal plasma flow and glomerular filtration will be obtained 24 hours post cardiac catheterization.

Progress: This study has had trouble being actively pursued due to time constraints of myself, Nuclear Medicine Service and significantly by inability to recruit patients from the Cardiology Service.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-50-90 Status: Completed

Title: Phase I Study of Intraperitoneal Cisplatin and Mitoxantrone.

Start date: 27 Mar 90	Estimated completion date:
Principal Investigator: Don W. Shaffer, MAJ	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
 Total number of subjects enrolled to date: 2
 Periodic review date: 20 May 91 Review results: Continue

Objective(s): 1.1 To determine the feasibility of administering a combination of mitoxantrone and cisplatin to the peritoneal cavity of patients with peritoneal dissemination of cancer or malignant ascites. 1.2 To characterize the hematological and non-hematological toxicity of cisplatin and mitoxantrone after intraperitoneal administration. 1.3 To evaluate patients for evidence of antitumor activity after the intraperitoneal administration of cisplatin and mitoxantrone. 1.4 To establish the maximum tolerated dosages of cisplatin and mitoxantrone when administered in combination to the peritoneal cavity.

Technical Approach: Mitoxantrone will be given every three weeks by abdominal catheter over 1-2 hours. Cisplatin will be given every three weeks along with Mitoxantrone. These treatments will be repeated every three weeks provided no severe side effects occur and the tumor does not increase in size. The responsiveness of the tumor to treatment will be assessed every three weeks on study.

Progress: Between BAMC (2) and UTSA (16), 18 patients have been enrolled. The maximal tolerated dose of mitoxantrone with cisplatin 100 mg/m² was 8 mg/m², One cPR UTSA) and 1 possible cPR/CR (BAMC) were noted. Protocol closed. Patient accrual has been reached.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-52-90 Status: Terminated

Title: An Open Label Study Regimen of Videx™ (2', 3'-Dideoxyinosine, ddI) in Patients with Acquired Immunodeficiency Syndrome (AIDS) Exhibiting Significant Deterioration while Taking Zidovudine (Retrovir®).

Start date: 24 Apr 90	Estimated completion date:
Principal Investigator: J. William Kelly, MAJ	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Infectious Disease	Associate Investigator(s): Craig T. Smith, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 21

Periodic review date: 1 Nov 91 Review results: Continue

Objective(s): To make ddI available to many patients with AIDS who are clinically deteriorating on AZT and cannot enter the Phase II ddI program due to protocol exclusion on geographic location.

Technical Approach: Treatment will consist of a reconstituted oral dose of ddI prepared according to instructions and administered every 12 hours on an empty stomach.

Progress: Twenty-one patients were enrolled. One patient died of unrelated causes. The study was terminated by the manufacturer when the drugs were approved for commercial release.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-63-90 Status: Ongoing

Title: Comparison of Adenosine, Dipyridamole, and Dobutamine Stress Echocardiography.

Start date: 15 May 90	Estimated completion date:
Principal Investigator: Timothy Martin, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Cardiology	Associate Investigator(s): John Seaworth, LTC, USAF, MC Joseph Johns, MAJ, MC Lawrence Pupa, MAJ, MC Williams Condos, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 8
 Total number of subjects enrolled to date: 40
 Periodic review date: Review results:

Objective(s): To compare the ability of adenosine (AD), dipyridamole (DI), and dobutamine (DO) echocardiography to detect coronary vascular disease and compare the incidence and degree of adverse effects following adenosine, dipyridamole and dobutamine administration.

Technical Approach: We compared AD, DI, and DO stress echo in 32 patients. Each received intravenous AD, DI, and DO in a single-blind random order. Two dimensional echocardiography was positive if abnormal wall motion was present at rest or during infusion. Coronary angiography was performed within six weeks of testing. Eight patients had single vessel disease (stenosis > 50%) and 16 patients had multivessel disease. Thirteen were taking beta blockers and 22 calcium channel blockers.

Progress: No annual report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-65-90 Status: Ongoing

Title: Treatment of Chronic Cutaneous Ulcers with Cultured Epidermal Autografts.

Start date: 15 May 90	Estimated completion date:
Principal Investigator: Jerome C. Hill, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Dermatology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
 Total number of subjects enrolled to date: 0
 Periodic review date: Review results:

Objective(s): To determine the suitability of autologous keratinocyte grafts for treatment of chronic cutaneous ulcers which have been refractory to standard therapy.

Technical Approach: Keratinocytes will be isolated from a small skin biopsy. The cells will be grown into stratified sheets and will be transplanted back to the patient from which the cells were obtained. The hypothesis to be tested: Can cutaneous ulcers which have not healed in spite of standard therapy be stimulated to epithelialize by using cultured epidermal autografts, even if the ulcer's base is the cortex of an underlying bone?

Progress: No annual report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-70-90 Status: Terminated

Title: Evaluation of Carboplatin and Mitoxantrone in Refractory or Relapsed Non-Hodgkin's Lymphoma and Hodgkin's Disease: A Phase II Study.

Start date: 7 Jun 90	Estimated completion date:
Principal Investigator: Don W. Shaffer, MAJ	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Hem Oncology	Associate Investigator(s): Timothy J. O'Rourke, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2
 Total number of subjects enrolled to date: 2
 Periodic review date: thru 31 Dec 92 Review results: Continue

Objective(s): To determine in a Phase II, single-arm trial the activity and toxicity of carboplatin and mitoxantrone together as a salvage regimen for refractory or relapsed lymphoma (Hodgkin's and non-Hodgkin's) patients.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Competing SWOG trials have limited accrual to this study. It will be closed now that Dr. Shaffer has gone to DDEAMC, Augusta, GA.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-71-90 Status: Ongoing

Title: High Dose Chemotherapy with Autologous Bone Marrow Support for Selected Advanced Solid Tumors.

Start date: 7 Jun 90	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 7
 Total number of subjects enrolled to date: 11
 Periodic review date: 20 Sep 91 Review results: Continue

Objective(s): To determine the toxicity, time to marrow reconstitution, responsive rate, and time to treatment failure of high-dose combination chemotherapy with carboplatin, etoposide, and cyclophosphamide followed by autologous marrow infusion in eligible patients with advanced metastatic solid tumors.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Three of seven patients achieved complete remission; three of seven patients achieved partial response; six of seven patients are still alive; two of seven remain in remission; one of seven died post-transplant due to lung toxicity; however, clinically his chest wall mass seems resolved. Autopsy was not granted by the family.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-73-90 Status: Terminated

Title: Phase II Study of the Treatment for Lymphoma with Cytosan and VP-16 for Cyto-reduction Followed by High Dose Chemotherapy Consisting of BCNU, ARA-C, Cytosan and VP-16 (BACE) with Autologous Bone Marrow Transplant.

Start date: 7 Jun 90	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Hem Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2
 Total number of subjects enrolled to date: 2
 Periodic review date: 16 Sep 91 Review results: Continue

Objective(s): To examine the efficacy and toxicity of cyto-reduction with Cytosan and VP-16 followed by high-dose chemotherapy consisting of BCNU, Ara-C Cytosan and VP-16 (BACE) with autologous bone marrow transplant for the treatment of lymphomas.

Technical Approach: Patients meeting the criteria for inclusion will be treated as outlined in the study protocol.

Progress: Study closed due to adverse reaction of patients on study.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-74-90 Status: Terminated

Title: The Incidence of Ambulatory Oxygen Desaturation in Patients with Chronic Obstructive Disease with and without Oxygen Therapy.

Start date: 7 Jun 90	Estimated completion date:
Principal Investigator: Wayne T. Honeycutt, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Pulmonary	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
 Total number of subjects enrolled to date: 4
 Periodic review date: Review results:

Objective(s): To determine 24 hour ambulatory oxygen saturation monitoring if constant low flow oxygen therapy is an effective method of preventing oxygen desaturation and if oxygen desaturation occurs in patients without room air hypoxemia.

Technical Approach: Phase I - Twenty-five patients meeting NOTT criteria for home oxygen therapy will undergo ambulatory oxygen saturation monitoring for 24 hours. Patients will wear an ambulatory pulse oximeter and Holter monitor. The 24 hour pulse oximeter and Holter monitor recordings will be examined to determine if periods of desaturation are associated with dysrhythmia.

Phase II - Twenty-five patients with chronic COPD seen in the pulmonary clinic who have a PO₂ less than 65 or FEV₁ < 1.0 L will be screened with ambulatory oximetry. A log will be used to correlate activity with episodes of desaturation. Patients will be studied with a Holter monitor the same as those in Phase I.

Progress: Study should be closed. Principal Investigator has left BAMC.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-77-90 Status: Ongoing

Title: The Effect of Early versus Delayed Entry of Coronary Artery Bypass Graft (CABG) Patients into a Cardiac Rehabilitation Program on Selected Measures of Cardiac Function, Cholesterol Levels, and Quality of Life.

Start date: 19 Jul 90	Estimated completion date:
Principal Investigator: Stacey Adams Dramiga, M.A.	Facility: Brooke Army Medical Center, Texas
Department/Service: Cardiac Rehabilitation	Associate Investigator(s): Antoinette Trafford, MAJ, AN James M. Gilman, LTC, MC Jean Johnson, PhD, RN
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
 Total number of subjects enrolled to date: 0
 Periodic review date: Review results:

Objective(s): a) Examine the relationship between time of entry into a cardiac rehab program and measures of physiologic stress, cardiac functioning, cholesterol levels, and quality of life in patients who have had coronary artery bypass graft surgery; b) evaluate the physiological outcomes of CABG patients at six weeks in a cardiac rehab program compared to the same measures after twelve weeks in the program; c) determine the effectiveness of a discharge instruction program of self-regulated activity compared to a comprehensive cardiac rehabilitation program.

Technical Approach: Subjects will be randomly assigned to Group I, entry into the program within 2 weeks after Hospital discharge and Group II, entry into the program 6 weeks after hospital discharge. A third group who live too far from BAMC to attend the Cardiac Rehabilitation Program but will be returning to BAMC for follow-up care will be used as a comparative group. All subjects will receive the same instruction on coronary risk factors, exercise and diet prior to discharge and will maintain a daily record of exercise conducted at home. Measures will be obtained on the four variables of interest prior to hospital discharge, after 6 weeks and 12 weeks in a Cardiac Rehabilitation Program (Groups I and II), and at 6 and 12 weeks post-hospital discharge (Group III).

Progress: Study is on hold for stress tests on the patients.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-78-90 Status: Ongoing

Title: Can Transesophageal Echocardiographic Screening for left Atrial Thrombi Preclude Routine Anti-Coagulation of Patients with Atrial Fibrillation before Cardioversion?

Start date: 19 Jul 90	Estimated completion date:
Principal Investigator: Armistead L. Wellford, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Cardiology	Associate Investigator(s): David M. Mego, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3
 Total number of subjects enrolled to date: 3
 Periodic review date: Review results:

Objective(s): Current medical practice dictates routine anticoagulation of patients with nonvalvular atrial fibrillation existing for three or more days prior to cardioversion. This exposes all patients, including those felt to be at low risk for embolus, to the risks of anticoagulation with Coumadin. We hypothesize that the use of transesophageal echocardiography in screening for the presence of atrial thrombi would preclude the need for routine anticoagulation in these patients.

Technical Approach: Patients with atrial fibrillation who are candidates for cardioversion will be randomized to treatment with (standard therapy group) or without Coumadin (experimental group) if the initial transesophageal echocardiogram shows no evidence of intra-cardiac thrombi. After 3 weeks, a repeat transesophageal echocardiogram will be done in order to judge the efficacy of Coumadin in resolving thrombi that may have been observed initially, and to examine the frequency of development of new atrial thrombi while treated or untreated with anticoagulants. After the second transesophageal echocardiogram, all patients without evidence of intra-cardiac thrombi would undergo cardioversion using oral antiarrhythmic agents and/or electrical cardioversion.

Progress: Three patients have been enrolled after finalization of data collection procedures and creation of a computerized database. 8-10 additional subjects have been enrolled at UTHSCSA. No complications reported.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-79-90 Status: Completed

Title: Phase I Evaluation of U73975 Brief Infusion Every 6 Weeks in Adult Patients with Solid Tumors.

Start date: 19 Jul 90	Estimated completion date:
Principal Investigator: Howard Burris, III, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s): Timothy J. O'Rourke, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3
 Total number of subjects enrolled to date: 11 BAMC, 30 UTHSCSA
 Periodic review date: thru 31 Dec 92 Review results: _____

Objective(s): 1) To determine the maximum tolerated dose of U-73,975 administered by a brief intravenous infusion every 6 weeks in adult patients with solid tumors. 2) to determine the qualitative and quantitative toxicity and reversibility of toxicity of U-73,975 administered in this fashion. 3) to investigate the clinical pharmacokinetics of U-73,975 and to evaluate the rationale for this schedule. 4) to determine the recommended dose and schedule for Phase II therapeutic trials of U-73,975. 5) to collect observations of the antitumor effect of U-73,975 when such events occur.

Technical Approach: Therapy will follow schema outlined in the study protocol.

Progress: This trial has completed accrual with a Maximum Tolerated Dose (MTD) defined at 180 mg/m². A total of 41 patients were enrolled, including 11 from BAMC. The dose-limiting toxicity (DLT) was myelosuppression, and no unexpected toxicities were noted. Antineoplastic activity was seen in patients with melanoma and gastric cancer. A manuscript is in preparation.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-90-90 Status: Ongoing

Title: Intensive Therapy and Autologous Bone Marrow Transplant with 4-HC Purging in Acute Myelocytic Leukemia (ACL) and Acute Lymphocytic Leukemia (ALL).

Start date: 30 Aug 90	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4

Total number of subjects enrolled to date: 4

Periodic review date: 1 Oct 92 Review results:

Objective(s): To determine the effects of autologous transplantations with 4-HC-treated marrow on hematopoietic reconstitution, actuarial relapse rate, and leukemia-free survival in pediatric and adult patients (< 65 y/o) with AML in second or third remission, and ALL in second or third remission.

Technical Approach: Fourteen patients under age 60 will be studied. Therapy will follow the schema outlined in the study protocol.

Progress: Four pediatric patients were purged and transplanted. Two of four are alive in complete remission.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-93-90 Status: Ongoing

Title: Serum Alpha Transforming Growth Factor Activity in Patients with Squamous Carcinoma of the Head and Neck.

Start date: 31 Aug 90	Estimated completion date:
Principal Investigator: Don Shaffer, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Hem Oncology	Associate Investigator(s): Howard A. Burris, III, CPT, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: <u>2</u>	
Total number of subjects enrolled to date: <u>2</u>	
Periodic review date: <u>thru 31 Dec 92</u> Review results: <u>Continue</u>	

Objective(s): 1) To determine the levels of serum and urine Alpha-TGF prospectively in patients with squamous head and neck cancer.

2) To determine if urine and serum levels of Alpha-TGF correlate with disease stage in patients with squamous head and neck cancer.

3) To determine if surgical removal of squamous head and neck cancer will result in a decrease in serum and urine Alpha-TGF.

Technical Approach: Blood and urine samples will be obtained and evaluated Alpha-TGF.

Progress: Only 4 patients have been enrolled in this trial. A total of 10 patients need to be accrued. Plans are to complete the study this year.

Detail Summary Sheet

Date: 21 Nov 91 Protocol Number: C-95-90 Status: Terminated

Title: Cardiopulmonary Response to Upright Exercise in Patients with Valvular Aortic Stenosis.

Start date: 31 Aug 90	Estimated completion date:
Principal Investigator: Robert Wozniak, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Cardiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 11
 Total number of subjects enrolled to date: 11
 Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the effect of valvular aortic on cardiopulmonary exercise performance.

2) To determine the relationship between ECHO/Doppler measurements and cardiopulmonary performance in patients with valvular aortic stenosis.

Technical Approach: Following Doppler/echocardiography patients will undergo upright cycle exercise, 20 W/min increments, symptom/limited, followed by cool-down exercise. During exercise blood pressure, heart rate and heart rhythm will be monitored.

Progress: Study terminated. Principal investigator PCS'd from Brooke Army Medical Center in 1992.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-99-90 Status: Terminated

Title: Efficacy of Passive Immunization in the Prevention of Infection Due To Klebsiella Pneumoniae and Pseudomonas aeruginosa. (Collaborative study with U.S. Army Medical Research and Development Command).

Start date: 7 Sep 90	Estimated completion date:
Principal Investigator: J. William Kelly, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Infectious Disease	Associate Investigator(s): Craig E. Smith, MAJ, MC James M. Lamiell, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 13

Total number of subjects enrolled to date: 13

Periodic review date: 16 Sep 91 Review results: Continue

Objective(s): 1) To determine the efficacy of intravenous immunoglobulin (IVIG) compared with albumin in reducing the incidence of infection caused by Klebsiella and P. aeruginosa bacterial serotypes contained in the two vaccines.

2) To determine whether IVIG delays onset or lessens severity of serotype specific infection.

Technical Approach: Patients entering an ICU or with chemotherapy-induced neutropenia who meet entry criteria will be randomized in a double-blind fashion to receive either hyperimmune IVIG or albumin. Patients will be followed for 6 weeks both clinically and microbiologically for the acquisition of infection and for survival. Serum specimens will be analyzed for levels of binding (ELISA) and phagocytic antibody, and bacteria will be serotyped to determine whether infection occurred with strains included in the vaccines.

Progress: Locally 22 patients were screened and 13 were randomized and treated without any adverse incidents. Nationally, there were several adverse reactions and some difficulty with the formulation dosage was noted by the Data and Safety Monitoring Board. The study was terminated by MRDC.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-104-90 Status: Completed

Title: Cardiopulmonary Response to Upright Exercise in Cardiac Transplant Patients.

Start date: 10 Oct 90	Estimated completion date:
Principal Investigator: Jay Gaucher, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Cardiology	Associate Investigator(s): Lawrence Pupa, MAJ, MC John Seaworth, LTC, USAF, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 35
 Total number of subjects enrolled to date: 35
 Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the effect of cardiac transplantation on the hemodynamic and metabolic response to maximal upright exercise in patients with dilated cardiomyopathy.

2) To characterize the hemodynamic and metabolic response to serial maximal upright exercise tests in patients with cardiac transplants.

Technical Approach: Patients with dilated cardiomyopathy under age 65 or patients with heart transplants are eligible for this study. Prior to cardiac catheterization, subjects will undergo bicycle exercise test. Following catheterization and with the catheter still in place a second bicycle exercise test will be performed. Blood pressure, heart rate, pressures inside the heart and lung, oxygen and heart rhythm will be monitored.

Progress: No further enrollment. No complications occurred. Results have been compiled and submitted as abstract (by Dr. Martin) to ACC (not accepted). He has plans to revise and submit elsewhere. Results show abnormal hemodynamic and metabolic response to maximal exercise in transplant patients compared with controls.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-107-90 Status: Ongoing

Title: Comparison of Foley Catheter with Standard Replacement Percutaneous Endoscopic Gastrostomy Tube: A Randomized Trial.

Start date: 10 Oct 90	Estimated completion date:
Principal Investigator: Michael A. Cassaday, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Gastroenterology	Associate Investigator(s): Shaliesh C. Kadakia, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To evaluate the longevity and durability of standard replacement gastrostomy tube in patients with previously placed percutaneous endoscopic gastrostomy (PEG).

Technical Approach: Approximately 100 patients will be studied consisting of two groups of 50 patients each, randomly assigned to receive either an all silicon Foley catheter or an all silicone standard commercial replacement kit. All patients who have a PEG will be offered enrollment in the study. All patients who require replacement of deteriorated or malfunctioning PEG tube will be the smaller group. The majority of the patients will have had a PEG placed for at least 4 weeks and have a mature tract between skin and the stomach. The initially placed PEG will be removed and replaced with either a Foley or a standard replacement tube. All patients will be randomized to either a Foley catheter or a standard replacement tube based on a computer generated randomization.

Progress: No annual report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-108-90 Status: Ongoing

Title: Phase I-II Trial of Hydroxyurea Using an Oral Intermittent Schedule in Patients with Squamous Carcinoma of the Head and Neck.

Start date: 24 Oct 90	Estimated completion date:
Principal Investigator: Howard M. Burris, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s): Timothy J. O'Rourke, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
 Total number of subjects enrolled to date: 4 BAMC; 19 UTHSCSA
 Periodic review date: thru 31 Dec 92 Review results: Continue

Objective(s): 1) To determine the qualitative and quantitative toxicities of Hydroxyurea given orally in a intermittent schedule every 3 days in patients with recurrent or metastatic squamous cell carcinoma of the head and neck.
 2) To determine the maximum tolerable dose in patients with recurrent or metastatic squamous cell carcinoma of the head and neck using this schedule.
 3) To determine the response rate of hydroxyurea in patients with recurrent or metastatic squamous cell carcinoma of the head and neck using this schedule.
 4) To characterize the pharmacokinetics/pharmacodynamics of hydroxyurea on this schedule.

Technical Approach: In order to be eligible for this study patients must have a histologically proven squamous cell carcinoma of the head and neck region that has persisted or recurred following definitive surgery and/or radiation therapy, and is not curable by other forms of therapy. Patients with metastatic disease are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: A total of 23 patients have been enrolled in the trial including 4 at BAMC. A MTD of 140 mg/kg has been identified with a dose-limiting toxicity of myelosuppression. An additional 2-3 patients will be entered at this level to better define the tolerance.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-2-91 Status: Completed

Title: Correlation of Active and Dropout Cardiac Patients in a Rehabilitation Program on Quality of Life and Rehospitization.

Start date: 8 Nov 90	Estimated completion date:
Principal Investigator: Stacey A. Dramiga, M.A.	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Cardiology	Associate Investigator(s): Kathleen A. Westphal, MAJ Kenn Finstuen, Ph. D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 140
 Total number of subjects enrolled to date: 140
 Periodic review date: Review results:

Objective(s): To determine the effect of continuance on a cardiac rehabilitation program on measures of quality of life, rehospitization, and risk factor modification in patients who have had coronary bypass grafting surgery or suffered a myocardial infarction.

2) To evaluate the effectiveness of self-regulated activity and risk factor modification, when compared to a continuous comprehensive cardiac rehabilitation program.

Technical Approach: This is a retrospective chart review and questionnaire. Group I will consist of patients who completed Phase II and continued to attend Phase II cardiac rehabilitation. Group II will consist of patients who completed Phase II but elected no to attend Phase II, but rather do their own home-based program.

Progress: All data has been entered into the computer and is awaiting statistical analysis.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-5-91 Status: Ongoing

Title: A Survey of Gastrointestinal Ulcerations for the Presence of Cytomegalovirus.

Start date: 23 Nov 90	Estimated completion date:
Principal Investigator: Robert N. Murray, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Gastroenterology	Associate Investigator(s): Allan L. Parker, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 25
 Total number of subjects enrolled to date: 25
 Periodic review date: Review results:

Objective(s): 1) To determine the overall prevalence of cytomegalovirus in ulcers of presumed acid-pepsin origin by endoscopic biopsy with immunofluorescent staining and viral cultures.

2) To establish whether a variable in endoscopic appearance presentation, or clinical course is useful in differentiating cytomegaloviral vs. acid mediated ulcer disease.

Technical Approach:

Progress: No annual report provided by principal investigator.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-11-91 Status: Ongoing

Title: The Effect of Oxygen Breathing Upon Lung Machines in Patients with Emphysema.

Start date: 3 Feb 93	Estimated completion date:
Principal Investigator: James E. Johnson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/ Pulmonary	Associate Investigator(s): Kevin Kimke, CPT, MC Wayne Honeycut, MAJ, MC H.M. Blanton, MAJ, MC Gregg T. Anders, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 40
Total number of subjects enrolled to date: 58
Periodic review date: 19 Oct 92 Review results:

Objective(s): To study the effects on lung mechanics of breathing 50% oxygen balance nitrogen versus breathing 21% oxygen balance nitrogen in a group of emphysematous patients with moderately severe disease.

Technical Approach: Patients undergo forced vital capacity, thoracic gas volume, airway resistance and compliance measurement before and after breathing 21% O₂ and 50% O₂ (double-blinded).

Progress: A total of 20 emphysema patients and 20 normals were studied in the manner described. As expected, the emphysema patients had a small reduction in compliance with breathing oxygen (about 6% P<.05) A surprising finding was that the normals had a mean increase in lung compliance (P<.05). The differences in responses in the 2 groups was highly significant (P<.01). This data has been presented at the Letterman meeting. A manuscript will be ready for publication in 6-8 weeks.

In addition, just the spirometry aspects of the study were repeated in greater detail in 18 additional patients. It was found that pure oxygen reduced the FEV₁ and MVV by about 6%. A manuscript has been submitted to the American Review of Respiratory Disease (already approved by CI) with these findings.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-12-91 Status: Ongoing

Title: The Effect of Magnesium on Ventricular Rate Control in Atrial Fibrillation.

Start date: 11 Dec 90	Estimated completion date:
Principal Investigator: Janet V. Hays, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Cardiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 9
 Total number of subjects enrolled to date: 9
 Periodic review date: Review results:

Objective(s): 1) To assess the immediate degree of rate control achieved with parenteral magnesium in patients with atrial fibrillation with a rapid ventricular response.

2) To assess the cumulative degree of rate control achieved at four hours with parenteral magnesium and digoxin in patients with atrial fibrillation with a rapid ventricular response.

Technical Approach: This study will examine the immediate effect of an intravenous bolus of magnesium sulfate on the ventricular response in patients with atrial fibrillation. It will also examine the combined effect of magnesium and digoxin on these same patients. It is expected that magnesium alone will cause an immediate decline in the ventricular rate compared to the placebo-controlled group or that the magnesium-digoxin combination will provide significantly greater rate control in four hours than may be achieved by digoxin alone. Patients will be drawn from those admitted to the Telemetry or Coronary Care Units with atrial fibrillation who meet the inclusion criteria.

Progress: First objective obtained. Second objective still not statistically significant. Preliminary results being presented at American Heart Association and Army ACP; submitted for presentation.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-13-91 Status: Ongoing

Title: A Randomized, Double-Blind, Placebo Controlled Trial of the Effect of Lovastatin on the Incident of Primary Coronary Heart Disease in Patients with Mild to Moderate Elevations in Total and LDL-Cholesterol in Combination with Low HDL-Cholesterol.

Start date: 11 Dec 90

Estimated completion date:

Principal Investigator:
Joe M. Moody, LTC, MC

Facility:
Brooke Army Medical Center, Texas

Department/Service:
Department Medicine/Cardiology

Associate Investigator(s):

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____

Total number of subjects enrolled to date: _____

Periodic review date: _____ Review results: _____

Objective(s): To investigate whether chronic treatment with lovastatin in patients without clinical evidence of coronary heart disease, slight to moderately elevated total and LDL cholesterol and low HDL-cholesterol will decrease the rate of fatal CHD of nonfatal myocardial infarction over a period of at least five years.

Technical Approach: Participants will be asked to maintain a standard low-fat and low-cholesterol diet throughout the study under the guidance of a dietician. Participants will be randomly assigned to either the placebo group or treatment group. The later group will receive 20 or 40 mg of lovastatin. Following initial evaluation at the Wilford Hall Wellness Clinic, they will be asked to return at six week intervals for the first eighteen months and then every six months thereafter. Lab tests will be performed at every follow-up visit.

Progress: No report available at this time.

There have been no complications, misadventures or adverse drug reactions as defined by regulation. Specifically, there have been 110 patient withdrawals due to CPK or liver function elevations. Twenty-nine patients have been withdrawn (2%). Studies of similar nature have encountered withdrawal of eight to twelve percent with an average of ten percent. This withdrawal ratio is exceptionally low. None of the patients were withdrawn due to events attributable to the study medication. Due to lagging recruitment, approval to enroll civilians and civil servants was obtained from the Air Force Surgeon General as well as the Air Staff on 26 June 1991. Civilian participants do not become eligible for care in the military system by participating in this study.

Enrollment is now 18.2% complete with 1,225 men (84%) and 232 women (16%). Estimated completion date is May 1997.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-14-91 Status: Ongoing

Title: Active Immunization of Early HIV Patients with Recombinant GP-160 HIV Protein: Phase II Study of Toxicity Immunotherapy, In Vivo Immunoregulation and Clinical Efficacy.

Start date: 8 Jan 91	Estimated completion date:
Principal Investigator: J. William Kelly, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Infectious Disease	Associate Investigator(s): C. Kenneth McAllister, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: 47	
Total number of subjects enrolled to date: 59	
Periodic review date: 5 Nov 91 Review results:	

Objective(s): To conduct a Phase 2 trial of the recombinant human immunodeficiency virus (HIV) envelope glycoprotein, GP160 candidate vaccine, in patients with early HIV infection (Walter Reed Stage 1-2). Specific objectives include: 1) to continue to evaluate the immunogenicity and toxicity of this product; 2) to determine the parameters predictive of immuneresponsiveness; and 3) to determine the clinical efficacy of immunization with GP160 in the treatment of early HIV infection.

Technical Approach: As outlined in the study protocol.

Progress: A total of 144 patients in San Antonio have been enrolled (27-BAMC; 19-Ft Hood; 14-WBAMC; 84-WHAFMC). 16 patients have been disenrolled, either voluntary or due to failure to meet eligibility criteria. 118 patients have been randomized and vaccinated. There have been no complications, protocol violations, or adverse drug reactions to date.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-16-91 Status: Ongoing

Title: High Dose Cytosine Arabinose (HIDAC), Fractionated Total Body Irradiation (FTBI) and Autologous Bone Marrow Transplantation (BMT) to Treat Patients with Acute Lymphoblastic Leukemia (ALL) in Second Hematologic Remission: A Phase II Study.

Start date: 14 Jan 91	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Hem Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
 Total number of subjects enrolled to date: 0
 Periodic review date: Review results:

Objective(s): To determine the incidence of non-engraftment and of leukemic relapse in patients receiving autologous BMT (ABMT) following the ex vivo depletion of leukemic lymphoblasts from the autologous marrow using the immunogenetic purging technology.

Technical Approach: As outlined in the study protocol.

Progress: 1) Adult patient undergoing EMT at present time. 2) Pediatric patients transplanted/2 alive in CR.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-21-91 Status: Ongoing

Title: Prospective Correlative Clinical Trial of Response to 5-FU in a Newly Developed Chemoresponse Assay Versus Clinical Response to Continuous 5-FU Infusion in Patients with Refractory Breast Cancer.

Start date: 6 Feb 91	Estimated completion date:
Principal Investigator: Howard A. Burris, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Hem Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
 Total number of subjects enrolled to date: 1 BAMC; 47 UTHSCSA
 Periodic review date: thru 31 Dec 92 Review results: _____

Objective(s): To conduct a prospective correlative clinical trial of the newly developed ChemoResponse Assay in patients with refractory breast cancer.

Technical Approach: As outlined in the study protocol.

Progress: Competing SWOG trials have limited accrual to this study. The trial will remain open until enrollment is complete. No unexpected toxicities have been observed.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-28-91 Status: Ongoing

Title: Exercise Induced Oxyhemoglobin Desaturation as a Predictor of Nocturnal Desaturation in Chronic Obstructive Pulmonary Disease Patients.

Start date: 6 Feb 91	Estimated completion date:
Principal Investigator: Wayne T. Honeycutt, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Pulmonary	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 13

Total number of subjects enrolled to date: 33

Periodic review date: 19 Oct 92 Review results:

Objective(s): To determine whether exercise induced oxyhemoglobin desaturation in moderate to severe chronic obstructive pulmonary disease (COPD) patients can predict those who will have significant nocturnal desaturation.

Technical Approach: Approximately 40-50 subjects will be studied. Each patient will undergo an initial history and physical examination. Pulmonary function tests will be performed on the SensorMedics Horizon System to include pre- and post-bronchodilator forced vital capacity (FVC) and FEV1. Lung volumes and diffusion capacity for carbon monoxide will be measured. Resting arterial blood will be obtained in the supine position on room air. Desaturation with exercise will be evaluate during cardio-pulmonary testing using the Minolta Pulse-Oximeter. Nocturnal respiratory excursions, nasal airflow, ECG and oxyhemoglobin saturation will be monitored with an ambulatory system.

Progress: As before, this study has become a retrospective chart review of records from San Antonio State Chest Hospital. Thus far, the data continues to show that nocturnal desaturation is unusual without exercise desaturation. However, the awake RA PO₂ appears to be the best indicator of nocturnal desaturation with values less than 70 mm/Hg most commonly associated with this occurrence. We will try to get a total of 40-50 patients before publishing our results.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-31-91 Status: Completed

Title: Phase I Trial of RP-56976 Administered as a 6-Hour Infusion Every 21 Days.

Start date: 13 Feb 91	Estimated completion date:
Principal Investigator: Howard A. Burris, III, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 8
 Total number of subjects enrolled to date: 20 BAMC, 12 UTHSCSA
 Periodic review date: thru 31 Dec 92 Review results: _____

- Objective(s): 1) To determined the maximum tolerated dose of RP56976 administered as a 6-hour infusion given every 21 days.
- 2) To determine the qualitative and quantitative toxicities of RP56976 on this schedule.
- 3) To determine the recommended dose for RP56976 on this schedule in Phase II trials.
- 4) To characterize the pharmacokinetics/pharmacodynamics of RP56976.

Technical Approach: Eligible patients will be treated as outlined in the protocol.

Progress: A total of 78 patients, 20 at BAMC, have received therapy with RP56976 (Taxotere). A maximum tolerated dose (MTD) of 100 mg/M2 was achieved on the 6-hour infusion, and 115 mg/M2 on the 2-hour (amended) infusion. Dose limiting toxicities (DLT) was febrile neutropenia on the 6-hr schedule, and myelosuppression on the 2-hr schedule. Antineoplastic activity was noted in breast, ovarian, lung, pancreatic, and cholangiocarcinoma. Phase II trials are underway in a variety of malignancies. A manuscript has been accepted for the Journal of Clinical Oncology.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-34-91 Status: Ongoing

Title: Central Aortic Blood Pressure Variability During Cardiac Catheterization.

Start date: 28 Feb 91	Estimated completion date:
Principal Investigator: Bernard J. Rubal, Ph. D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Cardiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5

Total number of subjects enrolled to date: 5

Periodic review date: Review results:

Objective(s): Retrospective study to evaluate the variability in central aortic systolic, diastolic and mean blood pressures to within ± 1 mm Hg in a consecutive series of 500 patients registered in the high-fidelity hemodynamic tape library at Brooke Army Medical Center.

Technical Approach: This is a retrospective study in which archived data is processed, A/D converted and computer analyzed.

Progress: Only a small number of patients have been entered to date due to limited access to clinical hemodynamic recording systems. Progress has, however been made in computer analysis software for this project. A decision by medical maintenance to disconnect the physiologic recording system in the 3rd floor cath lab has temporarily made it impossible to review and digitize data from the archive library. This project will continue as soon as laboratory equipment is refurbished.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-37-91 Status: Ongoing

Title: Hemodynamics of Cardiac Pacing Mode and Site of Electrical Activation on Myocardial Performance.

Start date: 6 Mar 91	Estimated completion date:
Principal Investigator: David M. Mego, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/ Cardiology	Associate Investigator(s): James Gilman, LTC, MC Leo Padove, MAJ, MC Bernard Rubal, Ph. D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3
 Total number of subjects enrolled to date: 3
 Periodic review date: Review results:

Objective(s): To compare the effects of right atrial, right ventricular, and atrioventricular sequential pacing on cardiac output while employing different right ventricular pacing sites.

Technical Approach: During cardiac catheterization, two temporary pacemaker will be placed into the heart. During each pacing mode, pacing will be performed above the patient's control sinus rate at rates of 70 to 89, 90 to 109 and 110 to 129. Paired comparisons will be made of the average cardiac output during right atrial pacing with the average cardiac output during the four other pacing modes.

Progress: No report provided by principal investigator.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-38-91 Status: Ongoing

Title: Effect of Sclerotherapy on Gastric Emptying.

Start date: 6 Mar 91	Estimated completion date:
Principal Investigator: Allan Parker, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Gastroenterology	Associate Investigator(s): Oyewole Toney, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 7

Periodic review date: 25 Sep 92 Review results:

Objective(s): To determine the effect, if any, of esophageal sclerotherapy on gastric emptying.

Technical Approach: Patients seen by the GI Service for sclerotherapy will be referred to nuclear medicine for gastric emptying study. The study will be performed in the standard manner.

Progress: Preliminary results show significant delay in gastric emptying.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-51-91 Status: Completed

Title: A Phase I Chronic Oral Dosing Study NAVELBINE (Vinorelbine) in Patients with Refractory Solid Tumors.

Start date: 29 May 91	Estimated completion date:
Principal Investigator: Howard A. Burris, III, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3
 Total number of subjects enrolled to date: 12 BAMC; 18 UTHSCSA
 Periodic review date: thru 31 Dec 93 Review results: _____

Objective(s): 1) To determine the maximum tolerated dose of oral NAVELBINE when administered in a daily 21 day schedule.

2) To define the quantitative and qualitative toxicities of chronic, oral NAVELBINE administration.

Technical Approach: NAVELBINE will be administered daily for 21 consecutive days to patients with miscellaneous advanced, solid tumors. Washout periods of 7 to 21 days will be utilized between treatment courses, based upon resolution of expected hematologic and other possible toxicities. Cohorts of at least 3 patients will receive oral NAVELBINE at each dose level.

Progress: Closed 29 Aug 92. A total of 30 patients enrolled; 12 from BAMC have been enrolled in this study. Accrual has been completed and a maximally tolerated dose established at 40 mg/day. Dose-limiting toxicities were diarrhea and myelosuppression. Responses were seen to non-small cell lung cancer and breast cancer.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-52-91 Status: Completed

Title: Phase I Trial of VP-16 + Schering r-GM-CSF (SCH-39300) (IND 2783) in Patients with Advanced Malignancies.

Start date: 29 May 91	Estimated completion date:
Principal Investigator: Don W. Shaffer, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s): Timothy O'Rourke, LTC, MC Howard A. Burris, III, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4
Total number of subjects enrolled to date: 13 BAMC; 18 UTHSCSA
Periodic review date: thru 31 Dec 92 Review results: _____

Objective(s): To determine the maximally tolerated dose and toxicities of VP16 combined with r-GM-CSF in patients with advanced malignancy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This protocol met its accrual goal and was closed to accrual 22 Jun 92. A manuscript has been prepared and submitted to Cancer Research. An abstract has also been sent to the American Association for Clinical Research meeting. Antitumor responses were noted in non-Hodgkin's lymphoma and non-small cell carcinoma of the lung. The dose limiting toxicity was myelosuppression.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-57-91 Status: Ongoing

Title: Spontaneous Bacterial Peritonitis Following Elective Esophageal Variceal Sclerotherapy: A Prospective Trial.

Start date: 4 Jun 91	Estimated completion date:
Principal Investigator: John G. Carrougher, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Gastroenterology	Associate Investigator(s): Shailesh C. Kadakia, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To evaluate the incident of spontaneous bacterial peritonitis (SBP) after elective esophageal variceal sclerotherapy (EVS).

Technical Approach: All patients with previous variceal bleeding who are receiving elective EVS and have ascites on physical examination will be eligible for the study. Patients will be admitted to the hospital and, following detailed history and physical exam, a paracentesis will be done. This will be sent for total cell count, polymorphonuclear count, total protein and albumin, cytology, aerobic and anaerobic cultures, and gram stain. The diagnosis of SBP will be made if the PMN count is 250/mm3 or greater and/or positive ascitic fluid cultures.

Progress: No annual report provided by principal investigator.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-59-91 Status: Completed

Title: Efficacy of Nifedipine GITS in Essential Hypertension - A Study Using Ambulatory Blood Pressure Monitoring.

Start date: 4 Jun 91	Estimated completion date:
Principal Investigator: Dominic Marini	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/General Medicine	Associate Investigator(s): Timothy P. Endy, MAJ, MC Michael A. Berry, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 16
 Total number of subjects enrolled to date: 16
 Periodic review date: _____ Review results: _____

Objective(s): To use 24-hour ambulatory monitoring to evaluate the antihypertensive effectiveness of Nifedipine GITS in comparison to an equivalent dose of Nifedipine.

Technical Approach: Outpatients who are found to have diastolic blood pressures of greater than or equal to 90 mm Hg and less than 120 mm Hg as determined by standard sphygmomanometer and who meet Study criteria will be entered into the protocol. A prospective clinical trial using one treatment arm will be employed.

Progress: Study is complete. Principal Investigator has PCS'd and no report is available.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-61-91 Status: Ongoing

Title: Effects of Large Volume Paracentesis on Pulmonary Functions Tests

Start date: 4 Jun 91	Estimated completion date:
Principal Investigator: Carlos Angueira, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Gastroenterology	Associate Investigator(s): Shailesh C. Kadakia, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To determine the effects of large volume paracentesis on pulmonary functions in patients with ascites.

Technical Approach: The patient population will consist of inpatients who are admitted because of ascites causing abdominal discomfort or respiratory symptoms. Large volume paracentesis (LVP) is indicated in these patients as part of their treatment program. Pulmonary function tests (PFTs) will be performed prior to the LVP. These will include all lung flows and lung volumes. Arterial blood gases will be performed prior to and after PFTs. Ascitic fluid will be sent for cell count, chemistries and cytology.

Progress: No report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-62-91 Status: Ongoing

Title: Treatment of Refractory Ulcers in Epidermolysis Bullosa Using Cultured Epidermal Allografts.

Start date: 4 Jun 91	Estimated completion date:
Principal Investigator: Wallace B. Smith, CPT. MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/ Dermatology	Associate Investigator(s): Jerome C. Hill, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2
 Total number of subjects enrolled to date: 2
 Periodic review date: _____ Review results: _____

Objective(s): To successfully harvest and culture epidermal kartinocytes from the parent of a child with epidermolysis bullosa and develop a multilayer epidermal allograft to be used to cover nonhealing erosions.

Technical Approach: Epidermal allografts from cells obtained from a skin biopsy performed on the parent of a child with junctional epidermolysis bullosa will be isolated and grown. The cells thus obtained will be planted on plastic tissue culture plates containing Kartinocyte Growth Medium which has been developed for the growth of kartinocytes. We will attempt manipulations of the media to induce the growth of multilayer epidermal sheets which will be transplanted into nonhealing eroded areas on the child with junctional epidermolysis bullosa.

Progress: No report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-65-91 Status: Ongoing

Title: Phase I Trial of Tetraplatin Administered for Five Consecutive Days Every 28 Days.

Start date: 24 Jul 91	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2
 Total number of subjects enrolled to date: 2
 Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the maximum tolerated dose of Tetraplatin administered on a daily x 5 every 28 days schedule.

2) To determine the qualitative and quantitative toxicities of Tetraplatin on this schedule.

3) To determine the recommended dose for Tetraplatin on this schedule in Phase II trials.

Technical Approach: This is a phase I study of tetraplatin administered on a daily x 5 schedule. Dose levels are 1, 2, 3.3, 5, 7, 9, and 11 mg/m².

Progress: To date toxicities have included nausea and vomiting, controlled on antiemetics; myelosuppression manifested by leukopenia and thrombocytopenia; and possible peripheral neuropathy seen in one patient.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-66-91 Status: Completed

Title: Phase I Trial of Topotecan Administered on a 5 Day Continuous Infusion Schedule.

Start date: 24 Jul 91	Estimated completion date:
Principal Investigator: Howard A. Burris, III, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
 Total number of subjects enrolled to date: 9 BAMC; 23 UTHSCSA
 Periodic review date: thru 31 Dec 92 Review results:

Objective(s): 1) To determine the maximal tolerated dose of Topotecan given on a 3-day continuous infusion schedule.

2) To determine the qualitative and quantitative toxicities of Topotecan given on a 3-day continuous infusion schedule.

3) To determine the recommended dose for Topotecan on a 3-day continuous infusion schedule to be used in phase II trials.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This trial has been completed with a MTD defined at 1.60 mg/m2/day. Total of 32 patients enrolled; 9 at BAMC. The dose-limiting toxicity was thrombocytopenia, with no unexpected toxicities observed. Antineoplastic activity was seen in patients with non-small cell lung cancer and ovarian cancer. A manuscript is in preparation.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-68-91 Status: Ongoing

Title: High Dose Cyclophosphamide, Etoposide, and Carmustine with DTIC and Autologous Marrow Rescue for Myeloma and Relapsed or Refractory Lymphoma, A Phase I-II Study.

Start date: 30 Jul 91	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s): W. Jeffrey Baker, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: Review results:

Objective(s): 1) To determine the complete response rate and survival of patients with relapsed or refractory Hodgkin's and non-Hodgkin's lymphoma treated with maximum tolerated dose of DTIC in combination with high dose cyclophosphamide, etoposide, and carmustine with autologous bone marrow rescue.

2) To determine the complete response rate and survival of patients with multiple myeloma treated with the maximum tolerated dose of DTIC in combination with high dose cyclophosphamide, etoposide, and carmustine with autologous bone marrow rescue.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Initial problem was that DTIC was not available because the building of the manufacturer which is in Japan has burned down. Presently drug has been available, however we had no eligible patients for it.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-71-91 Status: Ongoing

Title: The Polymerase Chain Reaction in the Diagnosis of Histoplasmosis.

Start date: 30 Aug 91	Estimated completion date: Dec 93
Principal Investigator: John H. Schrank, Jr, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Infectious Disease	Associate Investigator(s): Victor V. Tyron, Ph. D. C. Kenneth McAllister, Jr., COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To apply the polymerase chain reaction (PCR) in the detection and rapid diagnosis of histoplasmosis.

Technical Approach and Progress: The project consists of two experimental Phases:

a. Sequencing of amplified DNA to identify *H. capsulatum*-specific 18S ribosomal gene sequences. At present, we have sequenced the entire 1700bp gene from the G186AS *H. capsulatum* strain. A unique extra 400 base pair area was identified which seems to be contained by only this strain. We are currently attempting to sequence other strains to see if they also contain this extra 400bp piece.

b. Amplification of *H. capsulatum* DNA using organism-specific primers from organism in culture. We have chosen several unique primers from the sequenced gene and are testing them and modifying the actual amplification process in an attempt to increase the sensitivity and specificity of the assay.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-72-91 Status: Ongoing

Title: Total Bowel Transit Time During Resting, Training, and Exercise Periods in Competitive Runners.

Start date: 30 Aug 91	Estimated completion date:
Principal Investigator: Michael Cassaday, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Gastroenterology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To determine the transit of an unabsorbable marker such as charcoal in competitive runners.

Technical Approach: Approximately 40-50 runners will be studied. They will be asked to ingest 2 ounces of activated charcoal (Inst Char) suspension in three different sessions while remaining on their usual diets, but the intensity of the training varied. Session one will be during a period of routine training; session two will be the day of the race; and session three will be after a 72 hour rest period.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-83-91 Status: Ongoing

Title: A Comparison of Exercise Tc-99m Sestamibi Myocardial Scintigraphy and Adenosine Tc-99m Sestamibi Myocardial Scintigraphy for Diagnosis of Coronary Artery Disease in Patients with Left Bundle Branch Block.

Start date: 30 Aug 91	Estimated completion date:
Principal Investigator: Douglas G. Ebersole, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Cardiology	Associate Investigator(s): James Heironimus, LTC, USAF, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 11

Total number of subjects enrolled to date: 11

Periodic review date: Review results:

Objective(s): To determine the comparative utility of two non-invasive testing protocols in diagnosing coronary artery disease in patients with left bundle branch block.

Technical Approach: Patients will undergo an outpatient Tc-99m sestamibi exercise treadmill test via routine exercise protocols. After appropriate time interval for decay of the previously administered isotope, the patients will undergo an intravenous infusion of 140 ug/kg/min for 6 minutes. Both tests will involve the injection of 25 mCi Tc-99m sestamibi after stress and at rest with SPECT imaging. Patients will then undergo heart catheterization which will be performed using standard techniques to include selective coronary angiography and left ventriculography.

Progress: Manuscript in press: American Journal of Cardiology Jan 93. Adenosine MIBI study found to be more specific than exercise for the diagnosis of CAD in patients with LBBB.

Funding requirements for FY 93 - none.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-84-91 Status: Completed

Title: Phase I, Open-Label Clinical Trial to Assess the Safety, Tolerance and Pharmacokinetics of Weekly Intravenous Dose of CPT-11, A semi-Synthetic Analog of Alkaloid Comptothecin in Selected Patients with Carcinoma.

Start date: 30 Sep 91	Estimated completion date:
Principal Investigator: Howard A. Burris, III, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s): Timothy O'Rourke, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1

Total number of subjects enrolled to date: 4 BAMC; 28 UTHSCSA

Periodic review date: thru 31 Dec 92 Review results: _____

Objective(s): To establish the maximal tolerated dose (MTD) of CPT-11 given as a weekly dose for four consecutive weeks; to determine the qualitative and quantitative toxicities of CPT-11 given as a weekly dose for four consecutive weeks; to characterize the pharmacokinetics of CPT-11 and to collect information about the antitumor effects of CPT-11 in patients with solid tumors.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: A maximally tolerated dose was established at 180 mg/m². A total of 32 patients were enrolled; 4 from BAMC. Dose-limiting toxicities were diarrhea and myelosuppression. Antineoplastic activity was seen in patients with refractory colon cancer. A manuscript has been submitted to the Journal of Clinical Oncology. Phase II trials in colon cancer are underway.

Detail Summary Sheet

Date: 4 Feb 93 **Protocol Number:** C-85-91 **Status:** Ongoing

Title: Open Label Dose-Tolerance Study of Intravenous Ilmofofosine Administered by a 120 Hour Continuous Infusion Every 21 Days to Patients with Cancer Refractory to Standard Treatment.

Start date: 30 Sep 91	Estimated completion date:
Principal Investigator: Howard A. Burris, III, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s): Timothy O'Rourke, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2
Total number of subjects enrolled to date: 2 BAMC; 23 UTHSCSA
Periodic review date: thru 31 Dec 92 **Review results:**

Objective(s): To determine the maximum tolerated dose of ilmofofosine when administered intravenously as a 120-hour continuous infusion every 21 days and to describe the toxicity of ilmofofosine when administered on the schedule described above.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: A maximally tolerated dose of 300 mg/m2/day has been achieved. Total of 25 patients enrolled; 2 from BAMC. Dose limiting toxicities included hepatotoxicity and pulmonary toxicity at the 450 mg/m2 dose level. Accrual continues with plans to increase the duration of infusion from 120 to 168 hours.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-86-91 Status: Terminated

Title: Safety and Efficacy of Amphotericin B Lipid-Complex in the Treatment of Cryptococcal Meningitis in Patients with the Acquired Immune Deficiency Syndrome.

Start date: 30 Sep 91	Estimated completion date:
Principal Investigator: J. William Kelly, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Infectious Disease	Associate Investigator(s): C. Kenneth McAllister, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: Review results: Terminated

Objective(s): To evaluate and compare the safety, and efficacy of 3 different dosage regimens of Amphotericin B Lipid Complex and to compare these with Fungizonem[®] in the treatment of patients with the acquired immune deficiency syndrome and cryptococcal meningitis.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study was terminated by manufacturer and FDA. No patients were ever enrolled.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-88-91 Status: Ongoing

Title: An Open Multicenter Randomized, Dose-Ranging Study Azithromycin in the Treatment of Disseminated Mycobacterium Avium-Intracellular Complex Infection (MAC) in Patients with Acquired Immune Deficiency Syndrome (AIDS).

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: James W. Martin, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Infectious Disease	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: Review results:

Objective(s): To evaluate the efficacy and safety of two doses of azithromycin given chronically for the treat of M. avium bacteremia in AIDS pateints.

TECHNICAL APPROACH: Therapy will follow the outline in the study protocol.

PROGRESS: No patients have been seen at BAMC in the past year.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-94-91 Status: Ongoing

Title: Evaluation of the Effect of Forceps Size on the Adequacy Specimens Obtained by Transbronchial Biopsy.

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: James E. Johnson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Pulmonary	Associate Investigator(s): Gregg T. Anders, MAJ, MC H.M. Blanton, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: 19 Oct 92 Review results: _____

Objective(s): To determine the relative diagnostic yield of bronchoscopic biopsy performed with either small or large smooth edged forceps.

Technical Approach: Each patient will have 3 biopsies done with the large and 3 biopsies done with the small forceps in randomized order. If more tissue is needed based on visual inspection of the material, one or more additional biopsies will be taken with each forceps. Biopsies taken with each of the two forceps will be submitted to pathology for examination. The pathologist will be blinded as to which forceps was used for each biopsy.

Progress: So far, the large forceps appear to be producing more tissue than the small (P=.055). The amount of alveolar tissue and the diagnostic yield appear better with the large forceps but these are even further from statistical significance.

We will continue the study to include about 30-35 total patients.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-3 Status: Completed

Title: The Correlation Between Laboratory Studies of Human Bone Marrow Aspirates and those Performed on Peripheral Blood

Start date:	Estimated completion date:
Principal Investigator: MAJ W. Jeffrey Baker, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Internal Medicine	Associate Investigator(s): MAJ Svetislava J. Vukelja, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 27
 Total number of subjects enrolled to date: 27
 Periodic review date: Review results:

Objective(s): To evaluate whether bone marrow aspirates can provide an accurate assessment of hemoglobin, hematocrit, platelet count, white blood cell count, glucose, BUN, creatinine, and electrolytes compared to samples of venous blood.

Technical Approach: Simultaneously obtained samples of venous blood and bone marrow aspirate were obtained in 27 patients. Three of the parameters that were measured (BUN, chloride, platelet count) were found to be equal in venous blood and bone marrow. This information might be useful in the future for patients with intraosseous infusion devices or in the emergency room where intraosseous infusions are sometimes used.

Progress: Twenty-seven patients were enrolled. A significant correlation was found between blood and bone marrow measurements for the following parameters. Chloride, BUN, and platelet count. The results of the study were published in abstract form in the proceedings of the American Society of Hematology, Nov 1992.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-5 Status: Ongoing

Title: Pharmacodynamic Doppler Determination of Mitral Valve Area in Patients with Significant Aortic Insufficiency

Start date:	Estimated completion date:
Principal Investigator: MAJ David M. Mego, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): LTC Joseph P. Johns, MC
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period: 2
 Total number of subjects enrolled to date: 2
 Periodic review date: _____ Review results: _____

Objective(s): To assess the hemodynamic effects of amyl nitrite in patients with combined mitral stenosis and aortic regurgitation, and to assess the accuracy of Doppler-determined mitral valve areas during these effects.

Technical Approach: Study will involve five patients with combined mitral stenosis and aortic insufficiency who are undergoing diagnostic cardiac catheterization.

Progress. Two patients were enrolled before our capability to perform high-fidelity catheterization was temporarily interrupted while awaiting construction of the 3rd floor cath lab.

Detail Summary Sheet

Date: 4 Feb 93
Terminated

Protocol Number: C-92-6

Status:

Title: Prevalence of Proximal Colonic Neoplasms in Average Risk Asymptomatic Patients with Negative Fecal Occult Blood Tests and Flexible Sigmoidoscopy

Start date:	Estimated completion date:
Principal Investigator: CPT Carl S. Wroblewski, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): LTC Shailesh C. Kadakia, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____

Total number of subjects enrolled to date: _____

Periodic review date: _____ Review results: _____

Objective(s): To determine the prevalence of colonic neoplasms in the proximal colon, an area which is not screened at the time of routine flexible sigmoidoscopy. We wish to determine the prevalence of colonic adenomas and carcinomas in average-risk patients over the age of 50 years who are asymptomatic, have negative fecal occult blood tests, and have no evidence of any colonic polyps or carcinoma by routine flexible sigmoidoscopy.

Technical Approach: Patient population will consist of asymptomatic average-risk patients over age 50 years who are seen/followed in the Internal Medicine and Gastroenterology Clinics. Three fecal occult blood tests will be performed with standard dietary/drug instructions. In order to be enrolled in the study, these fecal blood tests will be negative.

Progress: Terminated due to PCS of principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-11 Status: Ongoing

Title: Household Transmission of Hepatitis C Virus in Military Populations

Start date: Jan 92	Estimated completion date: Dec 95
Principal Investigator: LTC Shailesh Kadakia, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): MAJ Thomas Kepczyk, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: <u>12 - consisting of</u> Total number of subjects enrolled to date: <u>patients and 9 household</u> Periodic review date: _____ Review results: <u>contacts</u>	

Objective(s): Study will consist of enrolling anti-HCV-positive individuals and anti-HCV-negative individuals with a diagnosis of chronic NANB hepatitis and their household contacts.

Technical Approach: Three (3) index cases tested positive for anti-HCV. The serum samples were submitted for further testing to include anti-HCV by ELISA, as well as by RIBA and finally by PCR to detect HCV-RNA. These samples were obtained from 3 index cases and 9 additional household contacts. Total of 56 index patients from BAMC, FAMC, WRAMC, and TAMC have been included in the study with 84 household contacts.

Progress: Of the 50 index cases, all 50 tested positive for anti-HCV by RIBA. 34, or 68% tested positive by PCR for HCV-RNA. Of the 49 spouses, 6 tested positive by RIBA, and 4 by PCR. Of the 7 adult household contacts, none tested positive by RIBA, and none positive by PCR. Of the 27 children household contacts, none tested positive for RIBA, as well as by PCR. Therefore, of the total contacts of 83, 6 tested positive by RIBA, and 4 by PCR. In summary, the study shows that American military households, spouses but not children or other household contacts, of HCV infected index patients are more likely to be infected with HCV than are military blood donors. The study is intended to be continued to determine the long-term results and possibly include more patients.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-13

Status: Ongoing

Title: Use of APACHE II Score to Predict Length of Mechanical Ventilation in Medical Intensive Care Patients

Start date:	Estimated completion date:
Principal Investigator: CPT James M. Brassard, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease	Associate Investigator(s): LTC James E. Johnson, MC LTC Greg Anders, MC LTC Herman M. Blanton, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 79
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To determine in a prospective fashion the correlation of first day APACHE II scores in patients admitted to an intensive care unit for acute respiratory failure secondary to ARDS, COPD. Pneumonia or Cardiogenic Pulmonary Edema with eventual duration of requirement for mechanical ventilation.

Technical Approach: APACHE (Acute Physiology, Age, Chronic Health Evaluation) Scores were derived from data obtained within 24 hours of ICU admission for patients admitted with the diagnosis of nonoperative respiratory disease. Mean scores were determined for 3 groups. 1-not intubated, 2- mechanical ventilator <14 days; 3-mechanical ventilator >14 days.

Progress: We prospectively evaluated 79 consecutive patients with the diagnosis of nonoperative respiratory disease admitted to our medical or coronary ICUs. Two five patients were excluded. The remaining 54 patients were divided into three groups. Statistical analysis was performed using a 2-tailed t-test. Mean duration of ICU stay was 1.81, 8.38, and 27.53 days for Control, Group I and Group II patients respectively.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-14

Status: Ongoing

Title: Cell Culture Model to Test the Relative Independence of Cancer Cells to Reduced T3 Levels by Comparison to More Normal Cells

Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Carlin, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Endocrinology	Associate Investigator(s): Isidoro Chapa
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To determine if reversible hypothyroidism can be induced briefly in euthyroid patients, conceivably normal cells can be induced into a hypometabolic state while the diseased cells continue at their baseline or near baseline metabolic level.

Technical Approach: Cell cultures will be grown from prostate tissue recently removed with TURP by urology and documented prostate cancer present by pathological exam.

Progress: In the last year, we have experienced a lot of success with this project. Early on, we had evidence of cell cultures of cancer cells being independent of thyroid hormone and so switched to immune bladder cancer cell line. We did this because we realized the need for an intermediate step of an animal model (easier to inject an immune cancer line into a mouse with less rejection).

Our early results showed not only that cell cultures were independent of thyroid hormone but they actually were inhibited by thyroid hormone. This was presented to the Military Society of Laboratory Scientists meeting in February 1993 and published. This project is continuing and being repeated for publication in other journals. No complications or misadventures.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-16 Status: Ongoing

Title: Incidence and Distribution of Gastrointestinal Lesions in Patients with Iron Deficiency Anemia

Start date: Sep 91	Estimated completion date: 12 Jun 93
Principal Investigator: MAJ Thomas Kepczyk, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): LTC Shailesh Kadakia, MC
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 59
 Total number of subjects enrolled to date: 59
 Periodic review date: 12 Mar 93 Review results:

Objective(s): To evaluate the incidence and distribution of gastrointestinal (GI) lesions in patients with documented iron deficiency anemia by performing both upper and lower gastrointestinal endoscopy (EGD/colonoscopy), small bowel biopsy and enterolysis in patients without lesions at EGD and colonoscopy.

Technical Approach: One-hundred (100) patients over the age of 45, who present to the GI Clinic for evaluation of iron deficiency anemia of unknown etiology will be entered into the study.

Progress: 59 patients enrolled (31 Males-28 Females). No complications reported. 1) 41/59 (69%) had a potential bleeding lesion. 2) 33 (56%) had upper tract lesions. 3) 17 (29%) had lower tract lesions. 4) 9 (15%) had malignancies. 5) 9 (15%) had concomitant upper and lower tract lesions. 6) 50% of the lesions were asymptomatic. Preliminary data was presented at the Army ACP meeting Nov 92 in San Francisco.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-18 Status: Ongoing

Title: The Natural History of HIV Infection and Disease in United States Military Beneficiaries

Start date: 1 Feb 92	Estimated completion date:
Principal Investigator: MAJ J. William Kelly, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 131
 Total number of subjects enrolled to date: 131
 Periodic review date: _____ Review results: _____

Objective(s): a) To systematically document the natural disease progression in individuals with HIV infections in a general military population. b) To form a study cohort which will be eligible for participation in treatment protocols and for other studies related to specific aspects of the descriptive elements (natural history) of HIV infection.

Technical Approach: Proposal is to organize information in a data base now being routinely collected on HIV patients into a data base, henceforth referred to as the BAMC Natural History Study, in such a way that more scientifically valid information will be forthcoming and safeguards to patient confidentiality are met.

Progress: 131 BAMC patients have been enrolled to date. This protocol is a component of an overall Tri-service natural history study which now has a registry of over 1800 patients. While data collection continues, initial analysis has begun which hopefully will result in at least four abstracts for submission to the 10th Annual International AIDS Meeting in the summer of 1994.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-21

Status: Terminated

Title: Prediction of Nucleated Cell Recovery from Autologous Bone Marrow Harvest (ABMH)

Start date:	Estimated completion date:
Principal Investigator: MAJ Svetislav J. Vukelja, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s): CPT W.J. Baker, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ **Review results:** _____

Objective(s): To validate a mathematical model that predicts the harvest volume needed for adequate recovery (200 million nucleated cells per kg) as a function of bodyweight, cellularity, mid-harvest count and harvest volume.

Technical Approach: The prospective study will test the hypothesis that recovery predicted by the model is not significantly different from actual recovery. It will also estimate the probability of adequate recovery (200 million nucleated cells per ml) given that a volume equal to or greater than that predicted to be adequate by the model is harvested.

Progress: Terminated due to change in instrumentation.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-23

Status: Ongoing

Title: An Open-Label Multi-Investigator Comparative Study of the Safety and Efficacy of Cefipime and Ceftazidime in the Treatment of Hospitalized Patients with Septicemia

Start date:	Estimated completion date:
Principal Investigator: MAJ John H. Schrank, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s): COL C. Kenneth McAllister, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To evaluate the efficacy of cefepime (2 g q8h) versus ceftazidime (2 g q8h) in the treatment of patients with clinically and bacteriologically documented bacterial septicemia with or without a confirmed site of local infection. Emphasis is placed on the isolation of pathogen(s) from 2 or more sets of pretreatment blood cultures from patients with suspected septicemia. An additional objective is to achieve further experience concerning the safety and tolerance of cefepime compared to ceftazidime, with both agents administered as a 6-g total daily dose in patients with serious, life-threatening septicemia.

Technical Approach: This is an open-label, randomized, comparative, multi-center evaluation of the safety and efficacy of cefepime versus ceftazidime in the treatment of clinically and bacteriologically documented septicemia, with or without a confirmed site of local infection. Patients who meet the inclusion and pass the exclusion criteria will be randomly assigned to receive either cefepime or ceftazidime (1:1 randomization, cefepime:ceftazidime). It is anticipated that approximately 1000 patients (100 evaluable per treatment group) will be enrolled at 30 to 40 selected sites over a period approximately 12 months.

Progress: As of 1 January 1993, 24 patients had been enrolled in the study. Of those 24, 2 (8.3%) patients did not receive any study drug. One patient was disqualified because he had received more than 24 hours of pre-study antibiotics; the other patient had a blood culture which grew pseudomonas aeruginosa and was clinically felt to require aminoglycoside therapy. The remaining 22 patients met both inclusion and exclusion criteria, and were randomized to receive either ceftazidime or cefipime. Eleven patients (50%) were assigned to the cefipime arm and eleven (50%) to the ceftazidime arm. Ten of the eleven (91%) who received cefipime successfully completed at least ten days of therapy. The one patient who did not complete a full course was removed from the study because the organism isolated from her blood cultures was resistant to cefipime. She was successfully treated with the appropriate

C-92-23 (continued)

antibiotic regime. Of the eleven patients who received ceftazidime, eight successfully completed at least ten days of therapy. One patient was removed because of a protocol violation (He was discharged after seven days of therapy on an oral antibiotic.) The last patient expired during therapy. After thorough review of his chart, it was felt that his death was totally unrelated to the administration of the antibiotic. (This has previously been reported to the IRB committee.) One of the patients who successfully completed a full course of therapy with cefipime had two positive pretreatment blood cultures, and thus was classified as septicemic by protocol definition. Six of the ten were classified as bacteremic, with one positive pretreatment blood culture. Of the remaining three patients, two had urinary tract infection, and one had a pneumonia. Three of the patients who received a full course of Ceftazidime were septicemic, three were bacteremic, and two had urinary tract infection.

Reported adverse affects were minor in all cases, and reversible following discontinuation of the antibiotic. Three deaths, which previously had been reported to the committee were all felt to be totally unrelated to the administration of antibiotics. It is anticipated that we will enroll approximately another fifteen patients prior to completion of the study in June, 1993.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-24 Status: Completed

Title: Phase II Study of Alpha-Interferon (Roferon A) and Isotretinoin for Patients with Squamous Cell Carcinoma (SCC) of the Lung

Start date: 21 Oct 91	Estimated completion date: 29 Aug 92
Principal Investigator: MAJ David Rinaldi, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s): MAJ Howard A. Burris III, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
 Total number of subjects enrolled to date: 1
 Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the combined efficacy of subcutaneously injected Roferon-A and oral isotretinoin in terms of objective responses, changes in performance status, and survival in patients with recurrent and/or unresectable squamous cell carcinoma of the lung. 2) To determine qualitatively and quantitatively the toxicity of combined treatment with subcutaneous Roferon-A and oral isotretinoin and to assess the reversibility of this toxicity.

Technical Approach: Patients will be evaluated for eligibility by investigator to ensure that each patient meets the criteria outlined in Sections 4.1 and 4.2 have been satisfied and that patient is eligible for participation in this clinical trial. All eligible patients will receive treatment in accordance with the study protocol.

Progress: One patient was enrolled on this protocol at BAMC. The study has been closed with a response rate of less than 10%. It has been published in the Journal of Anticancer Drugs, April 1993.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-25 Status: Ongoing

Title: Randomized, Double-Blind Study Comparing Medroxyprogesterone Acetate and Placebo in Cancer Cachexia

Start date: Apr 92	Estimated completion date: Dec 94
Principal Investigator: CPT Karen J. Bowen, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s): LTC Timothy J. O'Rourke, MC
Key Words: Cachexia, Medroxy- progesterone, Cancer	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6
 Total number of subjects enrolled to date: 6
 Periodic review date: _____ Review results: Blinded study-no results to date.

Objective(s): 1) To evaluate the effect of medroxyprogesterone acetate (MPA) vs. placebo in patients with cancer and weight loss. 2) A secondary goal is to evaluate the quality of life in patients receiving MPA.

Technical Approach: Ninety (90) patients, 18 years of age and older, with unresectable or recurrent solid tumors will be randomized to one of two arms matching patients by performance status, ongoing chemotherapy, and tumor type. Eligible patients will be placed on one arm of the study to receive either MPA or placebo. Patients receiving MP will be treated with a dose of 400 mg given orally once daily. Treatment will continue indefinitely unless patients are removed from the study at the discretion of the treating physician.

Progress: Accrual has been slower than expected. No unexpected adverse events have occurred which have been attributed to the MPA. As the trial is blinded, no results are available.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-30 Status: Ongoing

Title: Regression of Metaplastic Esophageal Epithelium With Omeprazole

Start date: Feb 92	Estimated completion date: Jan 95
Principal Investigator: MAJ J. Murray Francis, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): CPT Richard J. Shaffer, MC LTC Shailesh Kadakia, MC CPT John G. Carrougner, MC
Key Words:	
Cumulative MEDCASE cost: \$1000	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 15

Total number of subjects enrolled to date: 15

Periodic review date: Mar 93 Review results: _____

Objective(s): To determine if regression of metaplastic esophageal epithelium (Barrett's esophagus) can be induced by utilizing a hydrogen proton pump inhibitor (Omeprazole) to create an achlorhydric environment.

Technical Approach: 80 patients will be enrolled. Age, sex, duration of disease and prior therapy will be noted for demographic data. Primary exclusion criteria will be due to an indeterminant gastro-esophageal junction by direct endoscopic observation. After complete information outlining the requirements for the study, the current FDA status of Omeprazole and other literature regarding long-term usage of Omeprazole, those subjects declining enrollment in the Omeprazole study group will serve as controls (as they are routinely undergoing annual surveillance). Those meeting endoscopic criteria will be randomized to omeprazole or H₂-blockers.

Progress: 12/15 on Omeprazole. 3/15 on high-dose H₂-blockers. 15/15 followed up at 3 months. 9/15 followed to 9 months. No change in Barrett's epithelium from baseline measurements or from reference tattoo noted at 3 and 9 months. No complications due to study. Data presented as abstract at Army ACP meeting 11/92; accepted as abstract for presentation at National AGA meeting in May 93.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-33

Status: Completed

Title: A Randomized, Double-Blind, Placebo-Controlled Parallel Group Comparison of Monotherapy and Combined Therapy of Benazepril 20mg Once Daily and Amlodipine 5mg Once daily in Black Patients with Essential Hypertension

Start date:	Estimated completion date:
Principal Investigator: MAJ Charles Farrington, MC	Facility: Brooke Army Medical Center
Department/Service: Internal Medicine	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To determine the antihypertensive efficacy and systemic tolerability and safety of the combination of benazepril 20mg and amlodipine 5mg once daily compare to benazepril 20mg OD alone and placebo for treatment of black patients with essential hypertension (mean sitting diastolic blood pressure >100 mm Hg and <115 mm Hg).

Technical Approach: Patients with mean sitting diastolic blood pressure > 100 mmHg and < 115 mmHg will be entered into the trial. Visit 1 will occur after stopping the previous antihypertensive treatment gradually and completely for at least two weeks. Visit 2 will occur after a two to four week, single-blind, placebo run-in period. Patients with mean sitting diastolic blood pressure > 100 mmHg and < 115 mmHg at Visits and 1 and 2 and a variability of < 10 mmHg in mean sitting diastolic blood pressure between Visits 1 and 2 will be randomized in a double-blind fashion to receive benazepril monotherapy 20 mg OD, amlodipine monotherapy 5 mg OD, the combination of benazepril/amlodipine 20/5 mg OD, or placebo OD for eight weeks.

Progress: Data collection completed. Not cost effective to change.

De Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-34 Status: Ongoing

Title: Phase I Trial of RF60475 Administered as a One-Half Hour Infusion Every 21 Days

Start date: 29 Jan 92	Estimated completion date: 15 May 93
Principal Investigator: MAJ Howard A. Burris, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 9Total number of subjects enrolled to date: 9

Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the maximum tolerated dose of RP60475 administered as a 1/2 hour infusion given every 21 days. 2) To determine the qualitative and quantitative toxicities of RP60475 on this schedule. 3) To determine the recommended dose for RP60475 on this schedule in Phase II trials. 4) To characterize the pharmacokinetics/pharmacodynamics of RP60475. 5) To collect information about antitumor effects of RP60475.

Technical Approach: This is a rising dose, open-label, Phase I study of RP 60475 utilizing a dosage regimen of a 1/2 hour intravenous infusion every 3 weeks. Standard methodology for a Phase I oncology study will be utilized. The dosage levels to be studied are 12, 24, 40, 60, 84, 110, 130, 156, and 180 mg/m².

Progress: Nine patients were enrolled on this protocol at BAMC. Accrual goals were met and the study will close on 15 May 93. Dose limiting toxicities were myelosuppression. Phase II trials are being planned.

Detail Summary Sheet

Date: 4 Feb 93 **Protocol Number:** C-92-36 **Status:** Terminated

Title: Does the Use of Computer-Assisted Electrocardiograph Interpretation Affect Patient Disposition from the Emergency Department

Start date:	Estimated completion date:
Principal Investigator: CPT Todd V. Panarese, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Internal Medicine	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ **Review results:** _____

Objective(s): To compare general patterns of patient disposition from the Emergency Department using physician or computer-interpreted electrocardiographs (ECGs) in the process of making appropriate admission and out-patient referral decisions.

Technical Approach: Patients who present to the Emergency Department (ED) will not directly participate in the study nor the outcome of their disposition sought. Prior to phase I, all ED physicians will be made aware of this study, and will be told that they should expect to see computer-generated interpretations printed at the top of some ED ECGs.

Progress: Study terminated. Principal Investigator has PCS'd from Brooke Army Medical Center.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-37

Status: Completed

Title: Open Label Dose Tolerance Study of Intravenous Ilmofofosine Administered Once a Day for Five Days Every Twenty-Eight Days to Patients with Cancer Refractory to Standard Treatment

Start date:	Estimated completion date:
Principal Investigator: MAJ Howard A. Burris III, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3
 Total number of subjects enrolled to date: 3
 Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the maximum tolerated dose of ilmofofosine when administered intravenously once a day for five days every twenty-eight days. 2) To describe toxicity of ilmofofosine when administered intravenously on the schedule described above. 3) To describe the pharmacokinetics of ilmofofosine and metabolite when administered intravenously. 4) To evaluate anti-tumor activity if observed.

Technical Approach: Doses for individual patients will be selected according to a modified Fibonacci search scheme. The initial dose will be 5 mg/m² administered as a 2-hr infusion once a day for five days every twenty-eight days. If no toxicity is observed after the fifth dose, two additional patients will be treated at the same dose level. The second and third patients will be observed for two weeks after the fifth dose before proceeding to the next dose level. The procedure will be repeated at each dose level until the first sign of any toxicity is observed.

Progress: Three patients were enrolled on this protocol at BAMC. Accrual goals were met and the study was closed on 22 Jun 92. Dose limiting toxicity was myelosuppression. Another Phase I trial is being done utilizing a prolonged infusion schedule.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-38 Status: Ongoing

Title: Pharmacokinetic Guided Phase I Evaluation of 7U85 Mesylate
Administered Intravenously as a Two-Hour Infusion Every 28 Days

Start date:	Estimated completion date:
Principal Investigator: MAJ Howard A. Burris II, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the maximum tolerated dose (MTD) of 7U85 mesylate when administered intravenously, as a two-hour infusion once every 28 days. 2) To define qualitatively and quantitatively the toxicities of 7U85 mesylate when administered as a single dose every 28 days. 3) To apply a pharmacokinetic guided dose escalation procedure, in which AUC is measured, in order to decrease numbers of patients to achieve the MTD. 4) To determine the basic pharmacokinetics of 7U85 mesylate by study of plasma and urinary concentrations of the agent in patients. 5) To collect information about the antitumor effects of 7U85 mesylate.

Technical Approach: This is a rising dose, open-label Phase I study of 7U85 administered as a two hour infusion every 21-28 days. Standard methodology for a Phase I oncology study will be utilized. This protocol was amended and revised to decrease the study dose of drug and to allow a more conservative dose escalation scale. G-CSF was added to the regimen to prevent prolonged neutropenia.

Progress: Two patients have been enrolled on this protocol at BAMC. Accrual is ongoing, current dose level is 225 mg/m².

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-39

Status: Completed

Title: A Phase II Multicenter Clinical Trial to Evaluate the Safety and Efficacy of a Single Administration Every Three Weeks (q3w) Schedule of DuP 941 (Biantrazole) in Patients with Advanced Breast Cancer

Start date: 13 Mar 92	Estimated completion date: 14 Jun 93
Principal Investigator: MAJ Howard A. Burris III, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6
 Total number of subjects enrolled to date: 6
 Periodic review date: _____ Review results: _____

Objective(s): 1) To characterize the pharmacokinetics of DuP 941 in patients with advanced breast cancer at a starting dose of 50 mg/m². 2) To determine intra-and interpatient variability in this population. 3) To Develop and validate a limited sampling strategy to further study the PK/PD relationship in Phase II and III patients. 4) To attempt to correlate pharmacokinetics with toxicity and clinical efficacy.

Technical Approach: This is an open-label, Phase II study of DuP 941 (biantrazole) administered as an IV injection every 21-28 days in patients with metastatic breast cancer. Standard methodology for a Phase II oncology study was utilized.

Progress: Six patients have been enrolled on this protocol at BAMC. Accrual goals have been met, and the protocol is closed to further patients. One patient remains on study. Responses have been seen in breast cancer patients, but the response rate remains to be delineated. Further Phase III testing and a phase I trial of Dup 941 and Taxol are being planned.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-41

Status: Ongoing

Title: Quantification of T3 Receptors in Human Cancer Tissue Compared to the Tissue from the Clear Margin of the Same Surgical Specimen

Start date:	Estimated completion date:
Principal Investigator: Kevin Carlin, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Endocrinology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): Patients whose medical care has already dictated a surgical procedure for diagnosis and/or therapy of a possible cancer will be considered as a possible candidate to enter the study. There will be no exclusion factors. The only impact to patients for participation is the tissue that was to be removed any will undergo additional analysis.

Technical Approach: Patients with known or strongly suspected cancers who are undergoing surgery for diagnosis and/or therapy will have postop examination and testing of a representative sample of their mass and the clear margin. Samples will have their T3 receptors quantified by a previously utilized, well documented method. If the hypothesis is correct, there should be a higher percentage of T3 receptors in the clear margin than in the cancer cells.

Progress: No progress report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93	Protocol Number: C-92-50	Status: Ongoing
Title: Technical Competence in Echocardiography		

Start date:	Estimated completion date:
Principal Investigator: CPT Lou Anne Wellford, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine	Associate Investigator(s): MAJ Landon Wellford, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ **Review results:** _____

Objective(s): To determine the ability of Emergency Medicine physicians to recognize pericardial effusions by echocardiography (echo) and to compare their performance before and after a brief training session.

Technical Approach: a) Subject Selection: Test subjects will consist of ten staff Emergency Medicine physicians and ten upper level Emergency Medicine residents (third and fourth post graduate years). b) Patient Selection: Patients with one of the following findings documented by echo will participate: 1) Normal control-i.e., no pericardial/pleural effusions. 2) Small pericardial effusion. 3) Moderate pericardial effusion. 4) Pleural effusion.

Progress: No annual report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-52 Status: Completed

Title: Sarcoidosis and Lyme ELISA.

Start date:	Estimated completion date: 01 Mar 93
Principal Investigator: MAJ Joseph T. Morris, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s): COL Robert N. Longfield, MC
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period: 25
 Total number of subjects enrolled to date: 25
 Periodic review date: _____ Review results: _____

Objective(s): To determine whether the blood test for Lyme Disease is positive in patients with a diagnosis of sarcoidosis.

Technical Approach: Patients with sarcoidosis followed in the Pulmonary Clinic at Brooke Army Medical Center are to be identified for potential enrollment in this study. A questionnaire will be given regarding past exposures, tick bites, living in Lyme endemic areas, or rashes consistent with erythema migrans. After informed consent is obtained, five milliliters of blood will be drawn and sent for Lyme ELISA measurement.

Progress: Twenty-five patients with sarcoidosis followed in the Pulmonary Clinic at Brooke Army Medical Center, San Antonio, Texas enrolled in the study. Eight were male and seventeen were female. Fourteen patients were Black and eleven were White. All of the patients had undergone either skin or bronchoscopy with transbronchial biopsy for a diagnosis of sarcoidosis. Six patients were on steroid therapy for the following reasons: treatment of progressive restrictive lung disease felt secondary to sarcoidosis (3 patients), progressive central nervous system sarcoidosis (1 patient), uveitis (1 patient) and part of the immunosuppressive regimen to prevent transplant rejection following single lung transplant due to end stage sarcoid lung disease (1 patient).

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-53 Status: Ongoing
 Title: Core Protocol for HIV Developmental Diagnostic (Adult).

Start date:	Estimated completion date:
Principal Investigator: MAJ J. William Kelly, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s): Donald S. Burke, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 90
 Total number of subjects enrolled to date: 90
 Periodic review date: 22 Mar 93 Review results:

Objective(s): a) To develop and evaluate new and/or improved laboratory methods for establishing the diagnosis of HIV, and to correlate detectable HIV virus, HIV antigen, and/or HIV nucleic acid in blood with clinical status. b) To develop and evaluate new and/or improved laboratory methods for assessing the virus-specific immune response to HIV infection, and to correlate detection of virus-specific antibody or cell mediated immune responses with clinical status.

Technical Approach: Under this protocol, the patient will be asked to give informed consent that his/her blood can be used for the general purpose of development and evaluation of virologic and immunologic techniques, and that his/her clinical records can be reviewed in order to correlate test results with his/her clinical condition. Solicitation of patients will be done in the Infectious Disease Clinic by a protocol manager on the Infectious Disease Clinic.

Progress: Approximately 90 subjects have been enrolled to date. Serum and cells from these patients have been banked for use in development of diagnostic methods.

Detail Summary Sheet

Date: C-92-54 Protocol Number: C-92-54 Status: Ongoing

Title: A Topical Barrier Substance for Allergic and Irritant Contact Dermatitis

Start date:	Estimated completion date:
Principal Investigator: CPT W. Bret Smith, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Dermatology	Associate Investigator(s): CPT Mark Bonner, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): Will a new topical skin barrier substance (trade name-Dermashield, Benchmark Lab) provide protection against allergic contact dermatitis from poison ivy resin and/or protect the skin from an irritant dermatitis? A random age group (18-60 years) of 10 people believed to have an allergic contact dermatitis to poison ivy will be studied using their forearms as a bilateral comparison (one arm with, and one without Dermashield applied prior to application of poison ivy resin and sodium lauryl sulfate).

Technical Approach: A random healthy population of 10 men and women aged 18-60 years believed to have an allergic contact dermatitis to poison ivy will be chosen. Each person will serve as their own control using one forearm to compare to the other.

Progress: No report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93	Protocol Number: C-92-56	Status: Completed
Title: Hair Iron Levels in Hemochromatosis		

Start date:	Estimated completion date: 22 Mar 93
Principal Investigator: LTC Allan L. Parker, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 12

Total number of subjects enrolled to date: 12

Periodic review date: _____ Review results: _____

Objective(s): To determine any difference in hair iron content of normal persons as compared to hemochromatosis patients.

Technical Approach: Patients seen by GI Service will be solicited to donate hair samples. These patients are to include normals, hemochromatosis patients, and patients with alcoholic liver disease and iron overload. A total of 12 participants will be included with four in each group.

Progress: Study completed. Hair iron was not related to the etiology of liver disease. Results being prepared for publication and presentation.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-58

Status: Ongoing

Title: Ketoconazole Absorption in HIV Infected Patients

Start date:	Estimated completion date:
Principal Investigator: MAJ Joseph Morris, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s): MAJ J. William Kelly, MC M. Patricia Joyce, MD C. Kenneth McAllister, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 25

Total number of subjects enrolled to date: 25

Periodic review date: Review results:

Objective(s): To determine if ketoconazole absorption is abnormal in patients with HIV infection.

Technical Approach: Approximately 20-30 subjects will be required, consisting of 10-15 healthy individuals as controls and 10-15 patients with HIV infection. Subjects will be drawn from the patients followed at the BAMC Infectious Disease Clinic. Subjects, as well as their medical records, will be reviewed to exclude the possibility of an opportunistic infection requiring prompt treatment. The controls will be healthy age and sex matched volunteers. Patients already on ketoconazole, terfenadine, H₂ blockers, and/or antacids will have the drugs discontinued 3 days prior to the study. After informed consent is obtained, a tablet of ketoconazole (200mg) with 200 ml. of water will be given to each participant. Venous blood samples will be drawn at 0.1, and 2 hours after the ingestion of the ketoconazole tablet.

Progress: 25 subjects (11 HIV patients with early state disease, 9 HIV patients with late stage disease, and 5 uninfected controls) have been enrolled. Although there was a small trend in the ketoconazole absorption with increasing stage of HIV disease, it was not statistically significant. In addition the values in all groups were within the accepted range of normal. An abstract has been prepared and submitted to the 33rd Interscience Conference on Antibiotics and Antimicrobial Chemotherapy.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-61 Status: Terminated

Title: Pre-education and Patient Response to 60 cm. Fiberoptic Sigmoidoscopy

Start date:	Estimated completion date:
Principal Investigator: CPT Robert A. Massa, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Internal Medicine	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To determine whether pre-education in the form of an audiovisual tape that explains the 60 cm. fiberoptic sigmoidoscopy (FOS) procedure in detail would favorably lessen patient discomfort or improve depth at penetration or examination time.

Technical Approach: We plan to randomly assign a total of fifty patients who are already scheduled to undergo a FOS procedure to two prospective groups consisting of 25 patients each. Group I, the control group, will undergo "pre-education" only to the extent routinely covered by the endoscopist in obtaining informed consent for the procedure. Group II, the study group, in addition will be asked to come to the Internal Medicine Clinic (IMC) just prior to their scheduled procedure to view a 20 minute audiovisual tape.

Progress: Study terminated. Principal investigator PCS'd from Brooke Army Medical Center.

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Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-63 Status: Completed

Title: Paradoxical Response of Dead Space Ventilation to Exercise in Unilateral Absence of a Pulmonary Artery.

Start date:	Estimated completion date:
Principal Investigator: MAJ James M. Brassard, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease	Associate Investigator(s): MAJ James E. Johnson, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To report a case of Unilateral Absence of a Pulmonary Artery presenting with dyspnea and evaluated by cardiopulmonary exercise testing.

Technical Approach: A retrospective review of inpatient and outpatient records, as well as PFT lab files will be performed with planned submission in abstract form for local and national scientific meetings as well as in case report form for journal publication.

Progress: Study completed. Data to be published at a later date.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-64 Status: Ongoing

Title: A Phase I Trial of OKT3 (Anti-CD3) Monoclonal Antibody After High Dose Chemotherapy and Autologous Bone Marrow Transplantation in Patients with Breast Cancer.

Start date:	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s): W. Jeff Baker, MAJ, MC Barbara Reeb, DAC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the toxicities as well as the maximum tolerated dose of OKT3 antibody given after high-dose chemotherapy and autologous bone marrow transplantation in patients with breast cancer. 2) To determine the effect of OKT3 antibody on lymphocyte reconstitution postgrafting compared to lymphocyte reconstitution that occurs without administration of OKT3 after tandem high-dose chemotherapy and autologous bone marrow transplantation in patients with breast cancer. 3) If tumors are easily assessible for biopsy, determination at the results of cytotoxicity assays on tumor cells using OKT3 stimulated as well as unstimulated peripheral blood lymphocytes from the patients.

Technical Approach: Study has not started. We do not have HSC approval.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-65

Status: Ongoing

Title: A Phase I Trial Of Toremifene and Doxorubicin in Patients with Advanced Malignancies

Start date: 13 Apr 92	Estimated completion date: 1 Jan 94
Principal Investigator: Howard A. Burris III, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 11

Total number of subjects enrolled to date: 11

Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the maximally protective dose (i.e., that dose associated with clinically acceptable, predictable, and reversible toxicity) of toremifene when administered concomitantly. 2) To determine plasma pharmacokinetics of toremifene and doxorubicin when administered concomitantly. 3) To determine the chemosensitizing activity of toremifene when administered with doxorubicin. 4) To assay tissue samples for toremifene concentrations, and expression of MDR (multi-drug resistance) and associated gene-products pre- and post-toremifene treatment. 5) To evaluate for clinical evidence of MDR reversal by restoration of chemotherapeutic responsiveness in doxorubicin refractory cancer patient. 6) To determine the recommended dose for toremifene when given with doxorubicin (60 mg/m²IV every 21 days) for Phase II trials.

Technical Approach: Patients with advanced or refractory solid tumors will be treated at each dose level of toremifene. Two patients will have been previously treated with doxorubicin, and two patients will not have been previously treated with doxorubicin. One patient from each of these 2 groups (prior or no prior doxorubicin) must be followed for 3 weeks with the second patient followed for a minimum of one week prior to proceeding to the next dose level.

Progress: Eleven patients have been enrolled on this protocol at BAMC. Accrual is ongoing, and the current dose level of toremifene is 600 mg. As expected, myelosuppression has been significant.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-68 Status: Ongoing

Title: Prophylactic Low Dose Coumadin and Antiplatelet Therapy in the Nephrotic Syndrome Secondary to Membranous Nephropathy.

Start date: Jul 92	Estimated completion date: Jun 97
Principal Investigator: Gail L. Seiken, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Nephrology	Associate Investigator(s): Steven F. Gouge, LTC, MC
Key Words: Nephrotic Syndrome Membranous nephropathy	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
Total number of subjects enrolled to date: 0
Periodic review date: Jan 93 Review results: N/A

Objective(s): 1) To prospectively examine the incidence of thrombotic events in patients with nephrotic syndrome secondary to membranous nephropathy. 2) To prospectively evaluate the role of low dose coumadin and antiplatelet therapy in the prevention of thrombotic complication of nephrotic syndrome secondary to membranous nephropathy. 3) To prospectively evaluate the benefit of anticoagulation in patients with documented thrombosis associated with the nephrotic syndrome of membranous nephropathy.

Technical Approach: This is a prospective, randomized study designed to evaluate the incidence of thromboembolic complications in patients with idiopathic membranous glomerulopathy, and the potential role for prophylactic low dose coumadin and antiplatelet therapy in the prevention of these complications.

Progress: No patients have been entered into study thus far.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-69

Status: Ongoing

Title: A Double-Blind, Randomized, Comparative, Multicenter Study of CI-983 in the Treatment of Community-Acquired Bacterial Pneumonia

Start date:	Estimated completion date:
Principal Investigator: MAJ Gregg T. Anders, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease	Associate Investigator(s): CPT Dan Loube, MC
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
 Total number of subjects enrolled to date: 0
 Periodic review date: Review results:

Objective(s): To evaluate the efficacy and safety of two dosage regimens of CI-983 versus cefaclor in the treatment of patients with community-acquired bacterial pneumonia.

Technical Approach: Double-blind trial comparing one antibiotic to another in community-acquired pneumonia.

Progress: No patients enrolled to date.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-70 Status: Ongoing

Title: The Prevalence of Colonic Neoplasms in Patients with Known Breast Adenocarcinoma

Start date:	Estimated completion date:
Principal Investigator: MAJ John Carrougner, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): CPT Karen Bowen, MC LTC Shailesh Kadakia, MC CPT Richard Shaffer, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 30
 Total number of subjects enrolled to date: 38
 Periodic review date: 15 Oct 92 Review results: _____

Objective(s): The purpose of this study is to determine the prevalence of colonic neoplasms in female patients with breast adenocarcinoma. We wish to determine if colonic neoplasms occur in greater frequency in patients with breast carcinoma than in a similarly matched control population. The information obtained from this study should be used to establish guidelines on colonoscopic surveillance in patients with breast cancer.

Technical Approach: Patient population will consist of all patients currently receiving care for breast adenocarcinoma in the oncology clinic at Brooke Army Medical Center. A letter will be sent to each patient soliciting participation. All participants will undergo colon screening to be accomplished by colonoscopy.

Progress: Preliminary results indicate no adverse outcomes although one patient was admitted for observation for prolonged abdominal pain; another was seen in the ER for abdominal pain after colonoscopy. Both patients did well without evidence of perforation. No difference to controls has been seen to date. The study is ongoing.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-73 Status: Ongoing

Title: Immunoglobulin and Lymphocyte Responses in Systemic Lupus Erythematosus Patients Following Immunization with Three Clinically Relevant Vaccines

Start date:	Estimated completion date:
Principal Investigator: MAJ Steven A. Older, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Rheumatology	Associate Investigator(s): MAJ Nicholas J. Battafarano, MC
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 21
Total number of subjects enrolled to date: 21

Periodic review date: Review results:

Objective(s): 1) To determine how SLE patients respond to immunization. 2) To determine if there is any difference between the multiple variables associated with the SLE patients who demonstrate an adequate response and those who demonstrate an inadequate response. 3) To identify clinically useful applications to immunization prescription in SLE patients. 4) To identify characteristics of the immunologic response that provide insight into the underlying pathophysiology.

Technical Approach: Approximately twenty SLE patients from the Rheumatology Clinic will be entered into the study. Evaluation and phlebotomy will be performed in the Rheumatology Clinic at Beach Pavilion.

Progress: To date, 21 patients have been enrolled, and 15 have completed the 1st limb (initial evaluation, vaccinations, and skin testing). Study results are dependent on antibody titers obtained at the second visit, so are not currently available. There have been no adverse events thus far and none is anticipated.

Detail Summary Sheet

Date: 4 Feb 93 **Protocol Number:** C-92-81 **Status:** Ongoing

Title: The Induction of the Alpha-Delta Sleep Anomaly and Fibromyalgia Symptoms in Athletes vs. Sedentary Controls; Correlations with Somatomedin-C

Start date:	Estimated completion date:
Principal Investigator: CPT Carol L. Danning, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine	Associate Investigator(s): MAJ Steven A. Older, MC MAJ Max Duncan, MC John Ward, Ph.D. I. Jon Russell, M.d., Ph.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ **Review results:** _____

Objective(s): Two questions will be posed: a) does prior physical conditioning protect against the development of fibromyalgia symptoms in sleep-deprived individuals, and b) does Somatomedin-C, a growth factor associated with both sleep and tissue healing, play a role in the pathophysiology of fibromyalgia?

Technical Approach: Thirty-two active duty military volunteers between the ages of 18 and 40 will be studied in two groups. Sixteen highly conditioned athletes (8 females and 8 males) will constitute the study group ("athlete group"). An Equal number of healthy but sedentary individuals, age and sex mathed, will serve as the control group ("sedentary group").

Progress: No annual report provided by principal investigator.

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Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-83 Status: Ongoing

Title: A Randomized Phase II/III Study of PIXY321 (GM-CSF/IL-3 S. cerevisiae Fusion Protein) or Placebo in Combination with DHAP as Salvage Therapy for Lymphoma

Start date: 28 Aug 92	Estimated completion date: 1 Jan 94
Principal Investigator: CPT Howard A. Burris III, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s): CPT Karen J. Bowen, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5
 Total number of subjects enrolled to date: 5
 Periodic review date: _____ Review results: _____

Objective(s): To compare the effectiveness of SC PIXY321 to placebo in reducing the serverity of chemotherapy-associated myelosuppression in patients with relapsed or refractory lymphoma treated with DHAP chemotherapy.

Technical Approach: This will be a multi-center, randomized, double blind, phase II/III study in which eligible patients will be randomized to received either 2 cycles of DHAP chemotherapy followed by a fixed dose of SC PIXY321 or 2 cycles DHAP chemotherapy followed by placebo.

Progress: Five patients have been enrolled on this protocol at BAMC. Accrual is ongoing. Data from the randomized portion of the trial has not been evaluated.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-85 Status: Ongoing

Title: Possible Hormone Manipulations in The Treatment of HIV Infections Using Variations in Cell Culture Medium to Test for Facilitators and Inhibitors from the Hormone Family

Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Carlin, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Endocrinology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To culture human T cells in a culture medium devoid of human or calf serum. This will allow full knowledge of what actually is necessary to culture T cells.

Technical Approach: Volunteers between ages 18-65 who are not pregnant will donate 10 ml of blood after signing a consent form. This 10 ml of blood will then undergo a process in order to culture normal human T cells. The 10 ml of whole blood will then be spun down to separate red blood cells from white blood cells. The buffy coat containing the white blood cells will then be removed and mononuclear leukocytes obtained via Ficoll-hypaque isopycnic centrifugation.

Progress: During the past year, we have successfully developed a serum free culture medium for T cells. The T cells are now living from 2-4 weeks in this medium. An early run gave a preliminary positive result with our initial hypothesis being proven (T cells once infected with HIV are independent of thyroid hormone levels in the cell culture medium). A repeat of this result done with better controls and under stricter methods also indicated these results.

We are now repeating this experiment in larger groups with results to be published if once again, T cells are found to be independent.

There are no complications/misadventures with all blood drawn only on subjects who also are part of the project.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-88 Status: Ongoing

Title: Validation of a New Doppler-Echo Method for Quantification of Mitral Regurgitation

Start date:	Estimated completion date: Jun 93
Principal Investigator: MAJ David M. Mego, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): CPT Sheri Y. Nottestad, MC LTC John W. McClure, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 17

Total number of subjects enrolled to date: 17

Periodic review date: Review results:

Objective(s): To correlate the mitral regurgitant flow volume as determined by two techniques -- 1) the difference between angiographic and thermodilution stroke volumes at cardiac catheterization, and 2) a newly described method using the product of the mitral regurgitant Doppler color flow jet area and time velocity integral.

Technical Approach: Study will involve fifty patients of age greater than 18 years with mitral regurgitation who are undergoing diagnostic right and left heart cardiac catheterization. These patients will have no other significant regurgitant valvular lesions.

Progress: 17 patients have been enrolled, 13 of whom had technically adequate studies. In this group, good correlations have been established between the angiographic grade of mitral regurgitation and the Doppler color flow jet diameter ($r=0.84$) and Doppler-derived regurgitant volume ($r=0.797$). We continue to enroll 1-2 patients per week.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-93 Status: Ongoing

Title: Phase IV Study to Evaluate the Effect of Intravention of Acute Hospital Admissions for Congestive Heart Failure

Start date:	Estimated completion date:
Principal Investigator: MAJ Lee B. Padove, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1

Total number of subjects enrolled to date: 1

Periodic review date: _____ Review results: _____

Objective(s): To evaluate the efficacy, safety, outcome, and length of stay for patients receiving intravenous milrinone compared to patients receiving dobutamine in the course of their hospital admissions for acute exacerbations of chronic heart failure.

Technical Approach: This is an open, parallel, randomized study of intravenous milrinone compared to dobutamine in patients who are admitted to the hospital with acute exacerbations of chronic heart failure. Study will include 125 cardiologists who will each treat a minimum of 4 patients for a total of approximately 500 patients. A three-month time period is allotted for the enrollment of the 4 patients.

Progress: At this point, only one patient has been enrolled and taken part in protocol. One other patient had agreed to participate, however, was transferred for heart transplantation prior to beginning protocol. There have been no completions to date. Just as our institution has had a slow enrollment, so have other institutions. The protocol is still ongoing and we are still seeking patients.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-94

Status: Ongoing

Title: Colon Carcinogenesis: Modulation by Dietary Intervention

Start date:	Estimated completion date:
Principal Investigator: LTC Shailesh Kadakia, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): 1) To assess the modulation of cellular proliferation in colonic crypts (a biomarker of colon cancer risk) by dietary supplementation with cellulose in patients identified at higher than normal risk of developing malignant colon cancer. 2) To determine if longer term dietary intervention (1 year or more) of the same supplements will result in a significant reduction in the recurrence of adenomatous polyps in the colon.

Technical Approach: Study will be conducted using a prospective randomized control trial. Two dependent variables will be measured: 1) proliferative zone height (PZH), the biomarker previously discussed in the Background and Significance Section and 2) recurrence rate of sporadic adenomatous polyps. The dependent variable, cellulose supplementation will be composed of three levels: 0, 15, and 25 grams/day above normal baseline intake level.

Progress: Data collection completed in May 93. No reportable results are available at this time.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-95 Status: Ongoing

Title: Phonocardiogram Analysis: A Comparison of Several Methods of Signal Decomposition

Start date: Jun 92	Estimated completion date:
Principal Investigator: Mr. James R. Bulgrin	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): B. J. Rubal, Ph.D. LTC Joe M. Moody, MC
Key Words: Time-Frequency Analysis Phonocardiography	
Cumulative MEDCASE cost: \$2000	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6
Total number of subjects enrolled to date: 6
Periodic review date: Review results:

Objective(s): Compare and contrast several digital signal processing (DSP) methods in analyzing phonocardiograms (PCGs) obtained from patients with normal heart function and a variety of cardiovascular pathologies.

Technical Approach: In collaboration with time-frequency researchers at UTHSC, Brooks Air Force Base, University of Michigan and Hughes Air Craft Co., we have adapted off-shelf software or developed customized code to process intracardiac heart sound data.

Progress: Six patients intracardiac phonocardiograms have been analyzed with Gabor and wavelet transforms as well as Order Statistic Methods. We plan to evaluate other techniques (e.g., Reduced Interference Distribution) and compare performances with a neural network.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-97

Status: Ongoing

Title: Prospective Study of Clinical Efficacy of Two Formulations of Verapamil in Hypertensive Patients

Start date:	Estimated completion date:
Principal Investigator: MAJ J. Grant Barr, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Nephrology	Associate Investigator(s): MAJ William Wright, MC
Key Words: Hypotension Calcium Channel Blocker	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To determine whether there are differences in efficacy, duration of action or side effects profiles of two different sustained release preparations of the calcium channel blocker. verapamil. The hypothesis is that there are no clinically significant differences in the two products and that their duration of action is similar.

Technical Approach: Prior to beginning of experimental phase of the study, patients will have objective and subjective data collected. Patients will not be on any calcium channel blocker during this period however, all medications they are taking will be recorded. Physical examination will include recording of blood pressure and informed consent will be obtained.

Progress: Administrative, patient care and readiness have been given priority over research at this time.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-98

Status: Ongoing

Title: Possible Etiology for Euthyroid Sick Syndrome

Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Carlin, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Endocrinology	Associate Investigator(s): Gerald Merrill, Ph.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): Patients admitted to Brooke Army Medical Center (BAMC) who are seriously ill will potentially become candidates in the study. Judgement will be made by TRISS and APACHE III evaluation (an independent established method of objectively scoring patients) within 12 hours of admission to BAMC surgical or medical ICU by the staff physician involved in the study.

Technical Approach: Thyroid hormone levels and Triac/Tetrac levels will be tested in ICU patients at admission, as well as at 3 to 4 days and 2 weeks after admission. Subjects will vary as to their primary problem but all will be significantly ill. Analysis will be done to see if their clinical course and thyroid function tests correlate with Triac/Tetrac levels.

Progress: This project has had difficulty in the last year with arranging for actual receptor counts. Due to this difficulty, the project is being switched to an antibody detection method versus using I131 tagged T3. This method appears to actually be less costly. There have been no complications or misadventures.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-99 Status: Completed

Title: Early User Test and Experimentation (EUTE) of the Schistosome Topical Antipenetrant

Start date: 22 Sep 92	Est comp date: 24 Sep 92
Principal Investigator: COL Larry E. Becker, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Dermatology	Associate Investigator(s): COL James H. Keeling, MC
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 48
 Total number of subjects enrolled to date: 48
 Periodic review date: _____ Review results: _____

Objective(s): To determine if the Schistosome Topical Antipenetrant (TAP) is operationally effective from the user's standpoint. The test results will be used to prepare an Expanded Test Report (ETR) to support an In-Process Review decision. The results will demonstrate the feasibility of using TAP and will identify the uncertainties of this item with regard to operational performance, training, human factors, and safety.

Technical Approach: The TAP will be worn by representative test personnel during simulated combat service support activities. Personnel involved in the testing will be representative of those who will use the solution, if fielded. The results will demonstrate the feasibility of using TAP on all doctrinally prescribed areas of the solder's skin and will identify uncertainties with regard to user acceptability and safety.

Progress: Forty-eight total study volunteers were enrolled in and completed the one-day study on 22, 23 or 24 September 1992. No evidence of any chapping, irritation, rash, or erythema of the skin or mucous membranes was observed.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-103-90 Status: Ongoing

Title: Childhood Cancer: Coping of Child and Parent and Correlates
(Collaborative Study with University of Texas Health Science Center).

Start date: 10 Oct 90	Estimated completion date:
Principal Investigator: Gail Hoevet, PhD	Facility: Brooke Army Medical Center, Texas
Department/Service: University of Texas Health Science Ctr.	Associate Investigator(s): Jean Johnson, Ph. D., R.N.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: 60
Periodic review date: _____ Review results: _____

Objective(s): To refine stress coping instruments for children with cancer and for their parents that were developed during the first phase of this program.

Technical Approach: Subjects will be identified in Children's Cancer Clinics a BAMC and Santa Rosa Medical Center. The children will be male or female between the ages of 6 and 14 with a diagnosis of leukemia, lymphoma or malignant tumor either the diagnosis, treatment or completion of treatment stage of the illness. Parents of these children will comprise the parent sample. Completion of the stress and coping, self concept and temperament questionnaires may take place in the subjects homes or in the clinic, whichever is most convenient.

Progress: Sixty subjects have completed the questionnaires for this study. There is missing data on ten subjects. Ten more subjects will be recruited and data collection will be complete. The remaining 10 subjects will be recruited from Santa Rosa Children's Hospital. Data collection at BAMC is completed. Data analysis will be complete by January 1993.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-18-91 Status: Ongoing

Title: Nursing Intervention Lexicon and Taxonomy Study.

Start date: 15 Jan 91	Estimated completion date:
Principal Investigator: Susan J. Grobe, U.T. Austin	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Nursing	Associate Investigator(s): Marsha Fonteyn, RN, MSN
Key Words: Nursing interventions Natural language analysis	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 13
Total number of subjects enrolled to date: 94 includes nurses from other sites
Periodic review date: 4 Jan 93 Review results: _____

- Objective(s): 1) What are the typical nurses intervention statements identified by nurses for chronically ill adult patients?
- 2) What information is used by nurses to formulate nursing intervention statements?
- 3) What are the patterns of information selected by nurses to formulate nursing intervention statements about chronically ill adult patients?

Technical Approach: Both the mathematical (COBWEB) and a semantics based (ID-3) approach to classification of the nursing interventions has been taken. The ID-3 approach resulted in a preliminary result of 89.5% accuracy in classification. Rules modification will be undertaken to improve the expert system's classification.

Progress: The overall adequacy of the preliminary automated classification provides promise for using this approach with nursing interventions. Further work is necessary in refining the expert system (ID-3) rules and data dictionary to achieve higher levels of correct automated classification. Currently in final data analysis and writing of articles for publication. NIH Funding scheduled to terminate 28 Feb 93.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-42-91 Status: Ongoing

Title: The Use of Physical Restraints in Hospitalized Elderly.

Start date: 2 Apr 91	Estimated completion date:
Principal Investigator: Mary Ann Matteson, Ph. D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Nursing	Associate Investigator(s): Jean Johnson, Ph. D., R.N.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 25
 Total number of subjects enrolled to date: 25
 Periodic review date: Review results:

Objective(s): To determine the risk factor and consequences related to the use of physical restraints in hospitalized older adults and to identify the nurses' rationale for the type and extent of use of physical restraint.

Technical Approach: This is a prospective, descriptive study that will consist of collecting data regarding hospitalized patients who are physically restrained, the restraints used, and the immediate physiological and psychological effects of the restraints. A control group of patients who are not restrained will be used to compare the differences. In addition, a questionnaire will be given to nurses to determine their reasons for using physical restraints.

Data will be obtained from the charts to determine demographic information, medical diagnoses and medications. Subjects will be given the Folstein Mental Status Exam, and the Rosenberg 10-item Self-Esteem Scale. The investigators will check the patient's skin for the presence of pressure sores and note the stage and size, take vital signs, obtain height and weight, assess activities of daily living (ADL) performance and assess pulmonary function (SaO₂) using a pulse oximeter.

Progress: No report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 **Protocol Number:** C-46-91 **Status:** Ongoing

Title: Performance Predictor for the U.S. Army Practical Nurse Course (Licensed Vocational Nurse/LVN) and the National Council Licensure Examination-Practical Nurse (NCLEX-PN).

Start date: 9 Apr 91	Estimated completion date:
Principal Investigator: Sarah C. Shine, LTC, AN	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Nursing	Associate Investigator(s): Maryann G. Edmondson, CPT, AN Debra D. Mark, CPT, AN
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ **Review results:** _____

Objective(s): To examine the relationship between a variety of independent variables (TABE test scores, Phase I GPA, GT Scores, Phase II GPA) and a) success in the U.S. Army Practical Nurse Course (PNC), b) performance on the NCLEX-PN.

Technical Approach: A descriptive, retrospective method will be used to conduct the study of 206 male and female PNC students with an age range of 19 of 37 years.

Progress: No report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 **Protocol Number:** C-63-91 **Status:** Ongoing

Title: Organizational Communications Assessment of the Department of Nursing (DON), Brooke Army Medical Center.

Start date: 17 Jul 91	Estimated completion date:
Principal Investigator: Carol A. Reineck, LTC, AN	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Nursing	Associate Investigator(s): Hiluard G. Rogers, MAJ, MS Darryll E. Stafford, MAJ, MS
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ **Review results:** _____

Objective(s): To assess the BAMC DON organizational communication practices.

Technical Approach: The organizational communication assessment will focus on written and verbal communication generated by the senior staff member level within the Department of Nursing. Units of analysis will include the following: a) non-participant observation during routine staff decision and information meetings, b) rhetorical analysis of written documents, c) results of a communication questionnaire, d) results of the Myers-Briggs Type Inventory, and e) semi-structured interviews of a sample of newly assigned personnel.

Progress: Data analysis is in progress.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-67-91 Status: Ongoing

Title: Comparison of Enlisted Personnel Who are Participating in the Stress Management Unit Program (SMU) with Those Who Have Not Participated in the Program.

Start date: 30 Jul 91	Estimated completion date: 30 Jul 92
Principal Investigator: Linda S. Hartssock, CPT, AN	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Nursing	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 100

Total number of subjects enrolled to date: 100

Periodic review date: _____ Review results: _____

Objective(s): To describe health locus of control, state and trait anxiety levels, self-esteem, personality characteristics, and stress/coping skills of enlisted personnel who are participating in the Stress Management Program compared to those who have not participated in the program.

Technical Approach: This descriptive study will explore the similarities and differences between those who use the Stress Management Program compared to those who do not on measures of: health locus of control, state and trait anxiety, personality characteristics, self esteem and stress management skills. Program will have a) lower self esteem, b) higher levels of state anxiety, and c) higher stress and more effective stress management skills than those who do not decide to participate in the program.

Progress: Data is being entered into the computer for analysis.

(Data collection phase has been completed). No complications with subjects completing the above questionnaires.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-70-91 Status: Completed

Title: The Effect of Multiple Wrappers on Steam Penetration in an AMSCO Eagle Series 2053 Pulsing Pre-Vac Autoclave.

Start date: 30 Aug 91	Estimated completion date:
Principal Investigator: Gerald W. Flannagan, MAJ, AN	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Nursing/Central Material Svc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____

Total number of subjects enrolled to date: _____

Periodic review date: _____ Review results: _____

Objective(s): To determine the point at which, when using multiple wrappers sterility can no longer be assured.

Technical Approach: 100 test packs consisting of freshly laundered hand towels folded to a size of approximately 12 x 9 inches and stacked to a height between 10 and 11 inches with a "Check a Clave" test sheet and a "Proof" biologic indicator placed in the center will be wrapped with sterilization wrappers. The packs will be divided into 10 subgroups, the first being wrapped with 2 sequential wrappers, the second with 4, the third with 6, etc. in increments of two wrappers until the final set is wrapped with 20 sequential wrappers. After marking each biologic monitor and autoclave test sheet with the number of wrappers to be used, the packages will be wrapped and randomly placed on a rolling shelf unit. As the autoclave is loaded, any empty space will be filled with a test pack randomly selected from the shelf unit.

Progress: Results of this study gives validity that if an instrument set or linen pack is delivered to the operating room with an extra wrapper or two, the probability for sterilization having occurred is uncompromised. This allows the practitioner to utilize specific item and reduce number of sets that must be re-sterilized and also reduces the delay in the surgical suite. The ability to use a set that has had an additional wrapper inadvertently placed on it will save the hospital and the patient money.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-8 Status: Completed

Title: A Comparison of Effects of Heparinized Saline and 0.9% NaCl With or Without Preservative on Maintenance of Peripheral Intravenous Access Devices (IVADs) in Medical Patients Over Age 50 at Brooke Army Medical Center: The pilot study.

Start date: 30 Oct 91	Estimated completion date: 1 Apr 92
Principal Investigator: LTC Carol Reineck, AN	Facility: Brooke Army Medical Center, Texas
Department/Service: Nursing	Associate Investigator(s): COL Barbara Covington, AN MAJ T. Shank, MS 1LT P. Inguito, AN L. Jordan, Ph.D., RN M. Carolla, RN
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 20

Total number of subjects enrolled to date: 20

Periodic review date: Review results:

Objective(s): 1) To determine the effectiveness of 0.9% sodium chloride w/benzyl alcohol preservative compared to heparin in maintaining IVSD patency and preventing local reactions. 2) To determine the effectiveness of 0.9% sodium chloride w/o benzyl alcohol preservative compared to heparin in maintaining IVSD patency and preventing local reactions.

Technical Approach: A randomized, double-blind, prospective design with subjects assigned to one of three groups: saline flush with preservative, saline flush without preservative, and heparin flush for maintenance of IVSD. A total sample size of 400 IVSD flush episodes provided the basis for data analysis. Patency and local reaction were evaluated using the BAMC Peripheral Intermittent Infusion Device Research Assessment Instrument.

Progress: Twenty female medical patients ranging in age from 51 to 88 years (mean = 73 yrs) participated in the study. Group A: Saline without preservative - N=6, Group B: Heparin - N=2, Group C: Saline with preservative - N=12. Results: 1) Saline without preservative kept devices patent and free of local reaction for 48 hours in all subjects. 2) Heparin kept devices patent for 72 hrs in all subjects;

C-92-8 (continued)

minor local reaction by 24 hrs in 1 subject. 3) Saline with preservative kept 92% of devices patent and free of local reaction for 24 hrs, 50% had mild local reaction at 48 hrs, 100% patent and reaction free at 72 hrs.

Detail Summary Sheet

Date: 4 Feb 93 **Protocol Number:** C-124-89 **Status:** Ongoing

Title: To Compare the Effects of Continuous Versus Cyclic Continuous Estrogen-Progestin Therapy on Fasting Serum Lipoproteins in Postmenopausal Women.

Start date: 31 Oct 89	Estimated completion date:
Principal Investigator: Clifford C. Hayslip, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ **Review results:** _____

Objective(s): To compare the effects of continuous versus cyclic hormonal replacement therapy on the fasting serum lipoprotein profiles (FLP) of post-menopausal women.

Technical Approach: One hundred postmenopausal patients routinely seen at the GYN clinic will be asked to participate in the study. Women who have been on cyclic ERT, women taking Premarin only, and women on no hormonal replacement will be the three study groups. Patients on cyclic ERT, will have baseline FLP drawn on days 1, 15 and 25 of the month. At this time these patients will be switched to continuous therapy, and their FLP rechecked after two months in continuous therapy. Patients on Premarin alone, and postmenopausal patients on no therapy will be asked to have a single baseline FLP performed prior to entering the study. At this time they will be placed on three months of cyclic therapy, followed by three months of continuous therapy. FLP will be performed on these patients in a similar manner on days 1, 15 and 25 of the third month of cyclic therapy, and at random a single time after two months of continuous therapy.

Progress: No progress was made due to deployment of principal investigator to Operation Desert Shield/Storm.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-49-90 Status: Terminated

Title: Fetal Breathing Movements, Prostaglandins, and Byproducts of Infection in Preterm Labor.

Start date: 27 Mar 90	Estimated completion date:
Principal Investigator: Andrew Fowler, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s): Arthur S. Maslow, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6
 Total number of subjects enrolled to date: 7
 Periodic review date: 20 May 91 Review results: Continue

Objective(s): 1) To establish or refute the proposal that the absence (or diminution) of fetal breathing motion during preterm labor is correlated with the local production of prostaglandins and/or their metabolites by the decidua (endometrium in contact with fetal membranes) or the fetal membranes; and 2) to determine if a decrease in fetal breathing motion correlates with the presence of bacterial cell wall products (lipopolysaccharide), and/or membrane markers of infection (IL-1B; Tumor Necrosis Factor) that are detectable in amniotic fluid.

Technical Approach: The study group will consist of pregnant females at 20-36 weeks of gestation in established preterm labor who have not yet been given tocolytic therapy. These patients will be treated according to standard institutional protocol for preterm labor. This includes blood and urine tests, an IV, ultrasound, amniocentesis, and medicines to stop labor. An additional serum sample will be obtained for PGFM will be drawn 6 hours after initial therapy. If there is evidence of intra-amniotic infection, or of fetal lung maturity, tocolysis will be stopped. Further serum samples will be drawn for PGFM at the times electrolytes are tested. Aliquots of amniotic fluid and maternal serum will be frozen within 8 hours of collection. At the end of the study period the specimens will be thawed and analyzed in batch runs. Comparisons of outcome, presence or absence of fetal breathing movements, and presence of PGE2, PGF2x, PGFM, LPS, IL1B will be made.

Progress: Study terminated due to failure to submit an annual research progress report.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-64-90 Status: Ongoing

Title: The Effects of Magnesium Sulfate Tocolysis on Electrolytes and Hormones of Calcium Hemostasis.

Start date: 9 May 90	Estimated completion date:
Principal Investigator: Paul M. West, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s): Arthur S. Maslow, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6
 Total number of subjects enrolled to date: 28
 Periodic review date: 20 May 91 Review results: Continue

Objective(s): 1) Establish in detail the extent of electrolyte and hormonal alterations caused by therapy with magnesium sulfate for the preterm labor versus the pre-eclamptic patient and their neonates. 2) Determine if such electrolyte and hormonal disturbances correlate with the type of intravenous fluids infused or concentration of magnesium sulfate given. 3) Demonstrate that despite probable statistically significant changes in some electrolytes and hormones, clinically significant events are extremely rare, in support of available anecdotal literature.

Technical Approach: This study will include 25-30 patients in preterm labor treated in the standard manner with magnesium sulfate. Urinary electrolytes, serum/urine osmolality, PTH, calcitonin, and anion gap will be evaluated. The control group will include 5-10 pre-eclamptic patients as positive controls and 5-10 normal patients as negative controls.

Progress: Data has been collected on 19 patients in premature labor and 9 patients with pre-eclampsia, all of whom were treated with intravenous magnesium sulfate. Comparisons of serum calcium and PTH levels at different levels of serum magnesium have been made and displayed with the use of scattergrams, establishing the best linear equation to fit the data and establishing the R value and P value of the relationships. A definitive inverse relationship between serum calcium and magnesium is demonstrated in all patients. The response of PTH to increasing mg# levels appears to differ between the two study groups; it increases in the PML group, but decreases in the pre-eclampsia group. I plan to collect data on patients in normal labor, not being treated with mgs04. to use as another control group. To my knowledge, there has been no complications or adverse effect on patient care as a result of this study. No funding in FY93 should be required to complete this study.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-15 Status: Ongoing

Title: A Comparison of the Effects of Transdermal Estrogen Replacement Therapy Versus Oral Estrogen Replacement Therapy on Serum Lipids.

Start date: Feb 92	Estimated completion date:
Principal Investigator: CPT Susan R. Gaire, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics/Gynecology	Associate Investigator(s): CPT Maria Perez-Montes, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5
 Total number of subjects enrolled to date: 5
 Periodic review date: Review results:

Objective(s): To determine if transdermal estrogen replacement produces cardioprotective changes in serum lipids. If so, that they are comparable to those changes produced by oral estrogen replacement in menopausal women.

Technical Approach: To prove that transdermal estrogen produces cardioprotective changes on serum lipids comparable to oral estrogen in menopausal females.

Progress: Progress hampered by the lack of time allotted for entering new patients and follow-up on them in my schedule. I am working on inviting more fellow residents to assist and I will probably pass this project on to another resident in my department because I will PCS in June of 1993.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-17

Status: Ongoing

Title: Postpartum Hypothyroidism: Prevalence, Symptomatology and Response to Treatment

Start date:	Estimated completion date:
Principal Investigator: CPT Jacqueline Thompson, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To determine the prevalence of postpartum thyroid disease and to measure the associated symptomatology. Further, to determine in a prospective randomized fashion whether treatment of postpartum hypothyroidism decreases morbidity.

Technical Approach: Postpartum women of all races and ages who present to the Brooke Army Medical Center OB/GYN Clinic for their 6-8 week postpartum check will be asked to enter the study. Those women with a previous history of thyroid disease requiring treatment will b excluded.

Progress: No report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-43

Status: Terminated

Title: Safety and Efficacy of Topical Muco-Cutaneous Medication (TMCM) for Vulvovaginal Candidiasis: A Multicenter Randomized Double-Blind Trial.

Start date:	Estimated completion date:
Principal Investigator: Manuel T. DeLosSantos, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To gain additional information relative to the safety and efficacy of Topical Muco-Cutaneous Medication in the symptomatic treatment and/or cure of Vulvovaginal Candidiasis (using a standard 8" OB/GYN applicator). A second objective is to obtain information relative to the effects of swabbing the mucosal surface of the vagina with a liquid placebo. The study will be double-blind to prevent bias. Safety and efficacy of both TMCM and the placebo will be determined.

Technical Approach: Approximately 140 female patients will be enrolled in this multicenter study. Patients will be screened by means of a medical history, physical examination and laboratory evaluation.

Progress: Study terminated because cytologics changed their pursuit in investigating patients in the military due to inability to obtain enough patients for study.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-44 Status: Ongoing

Title: Feasibility Study for the Fetal Heart Rate Monitor

Start date:	Estimated completion date:
Principal Investigator: COL Manuel C. Morales, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics/Gynecology	Associate Investigator(s): Dean C. Winter, Ph.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To determine if the technology applied in a previous study to measure the heart rate of soldiers wearing heavy protective gear (ref 1) can be applied to non-invasively monitor fetal heart rate during various stages of labor.

Technical Approach: Health low-risk patients between the ages of 18-35, approved for the study by a BAMC physician. Although not essential to the study, the preference is to measure patients who have had a previous healthy delivery.

Progress: No reportable data available at this time.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-49 Status: Ongoing

Title: A Prospective Randomized Study on the Efficacy of Oral Contraceptive Therapy in the Treatment of Ovarian Cysts

Start date:	Estimated completion date:
Principal Investigator: CPT Paul L. Jones, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics/Gynecology	Associate Investigator(s): LTC Clifford C. Hayslip, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To determine the efficacy of oral contraceptive therapy in patients with simple ovarian cysts and the rate of resolution of ovarian cysts as measured by transvaginal ultrasound. To determine whether serum LH and FSH levels are predictive of the response to treatment.

Technical Approach: Sixty women with adnexal cysts measuring greater than or equal to 2.0cm mean diameter on transvaginal ultrasound will be randomized to treatment or control groups. The treatment group will be placed on ethinyl estradiol (35 mcg) and norethindrone (1 mg) for two cycles. Patients will be evaluated every week for 4 weeks and then every 2 weeks until the cyst has resolved.

Progress: No annual report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 **Protocol Number:** C-15-91 **Status:** Ongoing

Title: Plasmacytoma of Appendix.

Start date: 30 Nov 90	Estimated completion date:
Principal Investigator: John P. Wohler, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pathology	Associate Investigator(s): Donald Shafer, MAJ, MC Nguyen H. Dich, LTC, MC Frank Robertson, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ **Review results:** _____

Objective(s): To investigate retrospectively a single case to demonstrate the neoplastic nature of a proliferation of plasma cells within the appendix-caecum.

Technical Approach: This will be a descriptive study.

Progress: No report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-20

Status: Ongoing

Title: Pagetoid Intraepithelial Malignancy and In Situ Transitional Cell Carcinoma Involving the Residual Penile Urethra Following Cystoprostatectomy for High-Grade Transitional Cell Carcinoma of the Urinary Bladder.

Start date:	Estimated completion date:
Principal Investigator: LTC Michael H. Enghardt, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Pathology	Associate Investigator(s): LTC Ian M. Thompson, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To determine via immunohistochemical procedures whether or not the pagetoid cells are of transitional cell origin and to explore possibilities of histogenesis of the pagetoid intraepithelial malignancy, specifically the possible relationship to the adjacent in situ transitional cell carcinoma and the preceding invasive transitional cell carcinoma of the bladder.

Technical Approach: It is to be determined whether or not Uro-9 and Uro-10 antibodies can be used with immunohistochemical systems applied to formalin-fixed paraffin-embedded tissues rather than frozen tissue. This shall be done with the avidin-biotin-peroxidase complex technique. The optimal conditions for consistent staining of fixed tissues need to be determined.

Progress: Application of immunohistochemistry to determine whether or not urothelial origin can be proven was not successful. Testing with control tissue from low and high-grade transitional all carcinomas and non-urothelial tumors using standard immunohistochemical methods was inconclusive. Urothelial-derived antibodies (Uro-series) apparently cannot be used on formalin-fixed tissue, even with use of enhancement techniques. The determination of all lineage from low and high grade urothelial tumors is germane to the success of this project. Furthermore, there are no reasonably specific surrogate biomarkers which can be exploited to study cell lineage in this case.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-34-85 Status: Ongoing

Title: Effect of Dietary Modifications on Weight Change in Obese Children with Different Insulin Response to Glucose and Leucine Challenge.

Start date: 29 Apr 85	Estimated completion date:
Principal Investigator: Chandra M. Tiwary, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Departments of Pediatrics	Associate Investigator(s): Juliann M. Walker, LT, MS
Key Words: Children, Obese	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5
Total number of subjects enrolled to date: 113

Periodic review date: 14 May 91 Review results: Continue

Objective(s): 1) To determine if specific dietary modifications can result in improved weight reduction in certain categories of obese children.

2) To develop a profile for these children by identifying common characteristics according to their insulin responses to tolerance testing.

Technical Approach: Eligible patients will have a complete history, physical, CBC, SMAC-20, oral glucose tolerance test (1.75 gm/kg, max. 100 gms); and oral leucine tolerance test (150 mg/kg). Subjects will be classified into elevated and normal insulin groups in accordance with their insulin response to glucose and leucine challenges. All participants will receive dietary instructions and will be provided with behavior modification instructions.

Progress: Five more patients were enrolled although the oral glucose and oral leucine tolerance test and the anthropometric data were collected, none of these patients completed the dietary survey part due to non-availability of the pediatric dietitian. A new pediatric dietitian arrived in January 1993 and depending upon the work schedule, we may be able to complete this part of study in some patients.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-79-87 Status: Ongoing

Title: Appetite and Pectin.

Start date: 9 Sep 87	Estimated completion date:
Principal Investigator: Chandra M. Tiwary, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words: Appetite Obesity	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 23

Total number of subjects enrolled to date: 131

Periodic review date: 14 May 91 Review results: Continue

Objective(s): 1) To determine if specific dietary modifications can result in improved weight reduction in certain categories of obese children.

Technical Approach: Subjects will be obese children (ages 6-18) attending the pediatric clinic. All subjects will be studied twice at least 3 days apart. Subjects will be given either orange juice or orange juice with pectin. The child will be asked to describe the degree of hunger on a scale of 1 to 20, giving a rating of 1 if most full and 20 if very hungry. The same scale will be used to rate hunger every hour for four hours. At the end of four hours, the child will be given ice cream and again asked to rate hunger. Saliva production will be measured on three times - before drinking the juice, 4 hours after drinking the juice, and 1/2 hour after eating the ice cream.

Progress: We studied 23 obese children; 13 children felt reduced hunger when they took pectin with orange juice as compared to when they drank orange juice alone. Four children showed no difference in appetite with pectin. Results are not statistically significant, but subjective feeling of mothers and behavior observation by me suggest that pectin did make a difference in appetite. I would like to study about 12 more patients to see if statistically significant results can be obtained.

Detail Summary Sheet

Date: 4 Feb 93 **Protocol Number:** C-24-88 **Status:** Ongoing

Title: Ceftriaxone for Outpatient Management of Suspected Occult Bacteremia.

Start date: 13 Jan 88	Estimated completion date:
Principal Investigator: James H. Brien, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: 66 (FY 90)
Periodic review date: 25 May 91 **Review results:** Continue

Objective(s): To determine the effectiveness of ceftriaxone in the outpatient management of children three to thirty-six months of age with suspected occult bacteremia.

Technical Approach: Children are randomized to receive either ceftriaxone IM, Augmentin PO with ongoing follow-up until fever and illness is resolved.

Progress: Due to the principal investigator's reassignment to Walter Reed Army Medical Center, this project has had no patients enrolled since last review.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-90-88 Status: Ongoing

Title: Phase I Study of Piritrexim in Children with Advanced Leukemia and Solid Tumors (A Multicenter Study under the Direction of Dr. Thomas E. Williams, Santa Rosa Childrens Hospital).

Start date: 22 Nov 88	Estimated completion date:
Principal Investigator: Allen R. Potter, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Timothy J. O'Rourke, LTC, MC
Key Words: Leukemia	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
 Total number of subjects enrolled to date: 0
 Periodic review date: 25 Feb 91 Review results: Continue

Objective(s): To define the maximum tolerated dose and the dose limiting toxicity when Piritrexim capsules are administered orally to children in a daily x 5 schedule repeated every three weeks.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: No reportable information available.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-37-90 Status: Ongoing

Title: The Incidence of Congenital Respiratory Syncytial Virus.

Start date: 12 Mar 90	Estimated completion date:
Principal Investigator: Howard S. Heiman, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Ian Carter, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): A prospective study to determine if respiratory syncytial virus can be transmitted congenitally, and the incidence of RSV in the newborn population. Study population will include all women who deliver at Brooke Army Medical Center and their newborns, both term and premature.

Technical Approach: All newborns will receive routine DeLee suctioning of oral and nasopharynx on the perineum or abdomen by obstetrics. The specimen will be sent to the area lab for RSV ELISA. On all newborns who are RSV ELISA positive acute and convalescent serum titers for RSV will be obtained.

Progress: No report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-62-90 Status: Ongoing

Title: High-Dose Chemotherapy with Autologous Bone Marrow Rescue in Children with Recurrent or Progressive Solid Tumors or Primary CNS Malignancies: A Phase II Study (Collaborative Study with Walter Reed Army Medical Center).

Start date: 15 May 90	Estimated completion date:
Principal Investigator: Allan R. Potter, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Glenn Edwards, MAJ, MC, WRAMC David Maybee, COL, MC, WRAMC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
Total number of subjects enrolled to date: 1
Periodic review date: 20 May 90 Review results: Continue

Objective(s): 1) To define the toxicities of a regimen of high-dose cyclophosphamide (CY), etoposide (VP-16), and carboplatin (CBDCA) with autologous bone marrow infusion in pediatric patients with recurrent or progressive CNS neoplasms or solid tumors.

2) To measure response rates in a group of patients with refractory solid tumors and CNS malignancies following high-dose chemotherapy and autologous bone marrow infusion.

Technical Approach: To be eligible for this study, patients must be < 21 years of age, have an estimated survival of at least 8 weeks, and have adequate blood counts prior to bone marrow harvest. Therapy will follow the schema outlined in the study protocol.

Progress: No report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-32-91 Status: Ongoing

Title: Evaluation of Cisapride (R 51,619) in Patients with Gastrointestinal Motility Disorders.

Start date: 20 Feb 91	Estimated completion date:
Principal Investigator: Judith O'Connor	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
 Total number of subjects enrolled to date: 1
 Periodic review date: _____ Review results: _____

Objective(s): To determine the effect of cisapride on the symptoms of unexplained upper abdominal pain, nausea, vomiting, anorexia, early satiety, bloating/distension in patients with gastrointestinal motility disorders.

Technical Approach: The patient will receive cisapride tablets or suspension 50 mg tid for six weeks. If improvement is observed, the patient may continue to receive cisapride on a long-term basis for up to 48 months.

Progress: No report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-2 Status: Ongoing

Title: Childhood Obesity: Incidence Density Among Childhood Military Dependents and Association of Obesity with the Duty Status of the Sponsor

Start date: Feb 92	Estimated completion date:
Principal Investigator: COL Chandra Tiwary, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words: Childhood Obesity Incidence, Duty Status	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 500
 Total number of subjects enrolled to date: 500
 Periodic review date: Review results:

Objective(s): To describe the incidence density of childhood obesity among the dependents of US Army personnel. The association between incidence of obesity and the active duty or retiree status of the sponsor will also be assessed.

Technical Approach: All children beyond the age of 1 year attending the pediatric and adolescent clinic of the Brooke Army Medical Center will be included in this study. Their order of birth, name, gender, date of birth/age, height, weight, the sponsor's social security number, rank, duty status (active duty or retired), year when retired from the military, age on retirement and the current age will be recorded.

Progress: About 500 forms have been returned. Parents do not want to be bothered with filling out the forms, thus this impedes data collection. I have not analyzed the data due to unavailability of a data entry clerk. Near the end of the study, I will facilitate data analysis.

Detail Summary

Date: 4 Feb 93 Protocol Number: C-92-4 Status: Terminated

Title: A Double Blind Randomized Comparison of Ondansetron (Zofran) and Metoclopramide (Reglan) in the Presentation of Cis-Platin Induced Nausea and Vomiting in Children.

Start date:	Estimated completion date:
Principal Investigator: CPT Leslie Oraziotti, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): LTC Allen R. Potter, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): 1) Evaluate the effectiveness of Ondansetron in decreasing nausea and vomiting in children undergoing cancer chemotherapy. 2) Comparison to the antiemetic effects of Metoclopramide in this same population. 3) Evaluate the side effects of Ondansetron.

Technical Approach: Study terminated. Principal Investigator has been transferred to Fort Hood, Texas.

Progress: Study terminated. Principal Investigator reassigned to Fort Hood, Texas.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-82 Status: Ongoing

Title: Blood Lead (Pb) Levels in Infants and Toddlers

Start date: Sep 92	Estimated completion date: '94
Principal Investigator: CPT Deborah Baumann, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s): LTC Allan Potter, MC Gea Miller, M.D. COL John D. Roscelli, MC
Key Words: Lead	
Cumulative MEDCASE cost: No additional funds	Estimated cumulative OMA cost: No additional funds
Number of subjects enrolled during reporting period: 332	
Total number of subjects enrolled to date: 332	
Periodic review date: 22 Mar 93 Review results:	

Objective(s): To ascertain the incidence of lead exposure in the military dependents attending 6, 12, and 24 month well baby clinics. We will screen the children with a 5-part questionnaire. Any 6-month old infant found to be at risk for Pb exposure based on answers to their questionnaire will receive a blood lead level. All 12 and 24 month old children will receive a blood lead level in combination with a questionnaire. The infants will receive followup care at Brooke Army Medical Center (BAMC) based on blood lead results to include: education on sources of Pb exposure, environmental evaluations, dietary modification, medical evaluations, and chelation therapy if needed.

Technical Approach: We propose a descriptive study to investigate the incidence of lead exposure in military dependents.

Progress: No complications or adverse reactions. No new risks. Study going well. To date, 160 6-month and 160 12-month infants. 24 months not done as BAMC does not do 24 months. To date, no elevated lead levels collected. All < 10. It appears that lead incidence is not a problem in our military dependents.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-96 Status: Completed

Title: Capillary Refill Time in the Normal Newborn

Start date: 1 Jul 92	Estimated completion date:
Principal Investigator: CPT Barton Cook, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s): LTC Howard S. Heiman, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 40
 Total number of subjects enrolled to date: 40
 Periodic review date: _____ Review results: _____

Objective(s): To determine neonates capillary refill time using four (4) techniques in a controlled clinical fashion. From this data we hope to obtain a standard, reproducible method of obtaining capillary refill time in the newly born, so that the limits of normal may be determined for clinical assessment of new born hypovolemia. The study population will include newborns admitted to the Newborn Nursery at BAMC during the time of this study.

Technical Approach: We propose a descriptive study, describing four methods of obtaining capillary refill time in newborns. We will analyze the data to determine if a method can be found that is statistically and clinically significant.

Progress: Two of the methods (light touch, standard weight) yielded sufficiently narrow ranges to make them clinically useful. The remaining two methods (heel-dependent, heel-raised) had ranges so wide to make them clinically useless. Of the two useful techniques, standard weight requires adjunctive equipment, and light touch does not. The difference between the two is not significant at the 99% confidence interval, using 0.25 seconds as the minimum clinically detectable difference in refill time. We conclude that the method described as light touch can be used as a standard reproducible method of obtaining capillary refill time in the newborn. Results 1.42 sec (SD=0.21 sec) are consistent with a widely used standard for adults, <2 seconds being normal.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-51 Status: Terminated

Title: Drug Interaction of Chloroquine and Cimetidine

Start date:	Estimated completion date:
Principal Investigator: Gary Boswell, MAJ, MS	Facility: Brooke Army Medical Center, Texas
Department/Service: Pharmacy	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To determine if oral co-administration of chloroquine and cimetidine leads to increased plasma levels of chloroquine.

Technical Approach: We propose to test this hypothesis in normal healthy volunteers drawn from military permanent party personnel at Ft. Sam Houston and civilian volunteers. Both male and female non-smoking subjects between the age of 18 and 50 will be enrolled. Subjects will be randomly placed in either the treatment or control group. No attempt at blinding will be made.

Progress: Study has been terminated due to ETS of principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-12-77 Status: Ongoing

Title: Intravenous Administration of I¹³¹ (NP59) for Adrenal Evaluation of Imaging.

Start date: 15 Nov 76	Estimated completion date:
Principal Investigator: James D. Hieronimus, LTC, USAF, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Radiology/Nuclear Medicine	Associate Investigator(s): Neil Katz, MAJ, MC
Key Words: Adrenal Scan	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
 Total number of subjects enrolled to date: 11
 Periodic review date: 16 Sep 92 Review results: Continue

Objective(s): Clinical evaluation of NP 59 as a diagnostic agent for the detection of adrenal-cortical disorders and as a potential scanning agent for detecting structural abnormalities of the adrenal medulla.

Technical Approach: This study will be performed on 50 patients after complete evaluation by the Endocrinology Service. The radiopharmaceutical will be administered by slow IV injection with a dose of 1 mCi in adults and 15 Ci/kg in children. Lugol's solution, 5 drops twice daily starting one day before injection and continuing for two weeks, will be used to block thyroid uptake of radioiodine. Images will be obtained on the 4th, 7th, and 11th day following injection using scintillation camera.

Progress: Correlation of imaging results with clinical findings/outcome has been good. However, clinical utilization of this agent has been limited. This study will be continued to provide this diagnostic tool.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-47-89 Status: Ongoing

Title: Evaluation of ¹³¹I-miBG (¹³¹I-meta-iodobenzylguanidine sulfate) in Patients Suspected of Having Pheochromocytoma, Paraganglioma or Medullary Hyperplasia.

Start date: 20 Mar 89	Estimated completion date:
Principal Investigator: James D. Heironimus, LTC, USAF, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Dept. of Radiology/Nuclear Medicine	Associate Investigator(s): Neil Katz, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 13
 Total number of subjects enrolled to date: 34
 Periodic review date: 20 May 91 Review results: Continue

Objective(s): To evaluate the use of ¹³¹I-miBG as an aid in the diagnosis, evaluation, and localization of pheochromocytomas, paraganglioma, neuroblastoma and/or adrenal medullary hyperplasia.

Technical Approach: Patients suspected of having pheochromocytoma, paraganglioma or medullary hyperplasia will be eligible. If upon careful consideration of the clinical history, examination and laboratory findings the patient is considered to have reasonable suspicion (>5% possibility) of any of the above conditions, they will be included for study by ¹³¹I-miBG scintigraphy.

Progress: This agent is proving to be accurate in the diagnosis of pheochromocytoma and neuroblastoma, though sensitivity in the latter is uncertain due to lack of positive cases. This study will be continued to provide this diagnostic tool.

Detail Summary Sheet

Date: 4 Nov 92 Protocol Number: C-108-89 Status: Ongoing

Title: Evaluation of Interstitial Lymphoscintigraphy with Radioactive Technetium Antimony Trisulfide Colloid (99m Tc-Sb₂S₃ for Lymphedema, Internal Mammary and Excised Malignant Melanoma Lymphoscintigraphy

Start date: 8 Sep 89

Estimated completion date:

Principal Investigator:
James D. Heironimus, Lt COL, USAF, MC

Facility:
Brooke Army Medical Center, Texas

Department/Service:
Department of Radiology

Associate Investigator(s):
Neil Katz, MAJ, MC

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 8

Periodic review date: 16 Sep 92

Review results: Continue

Objective(s): To determine the effectiveness of radioactive Tc99m Antimony Trisulfide Colloid in imaging lymph nodes.

Technical Approach: Patients will be selected and referred to Nuclear Medicine Service primarily by the Surgery and Oncology Clinic. For evaluation for lymphedema, intradermal injections of the radiopharmaceutical will be made in the distal extremities of interest. To evaluate the lymph drainage paths of a dermal region, injections will be made intradermally immediately adjacent to the site of the skin lesion/biopsy site. For all studies, scintigraphic imaging will be performed using an Anger Gamma Camera system. Multiple use of the appropriate areas will be attained immediately following the injection of the radiopharmaceutical as well as approximately 1-4 hours after injection. Body outlining and/or flood field imaging techniques will be performed to provide additional positional information.

Progress: This agent appears to be exceptionally effective in delineating the lymphatic drainage truncal regions. Clinical interest, however, has been limited. This study will be continued to provide this diagnostic tool. Problems over the past year creating an absence of studies include lack of clinical referrals and limited availability of the agent (transition of manufacturers).

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-126-89 Status: Terminated

Title: HM-PAO Brain SPECT in TIA as Predictor of Ischemic Infarction.

Start date: 31 Oct 89	Estimated completion date:
Principal Investigator: James Heironimus, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Radiology/Nuclear Medicine	Associate Investigator(s): Mary B. Hart, MAJ, MC Alan Halliday, MAJ, MC Wayne Gordon, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
 Total number of subjects enrolled to date: 0
 Periodic review date: Review results:

Objective(s): To prospectively investigate the usefulness of HM-PAO Brain SPECT as a predictor of permanent cerebral infarction in transient ischemic attacks.

Technical Approach: In a prospective series of patients presenting with transient cerebral ischemia, TC-99m HM-PAO brain SPECT studies will be obtained within 72 hours (of the TIA) and follow the clinical course over a three month period. Following Tc-99m HM-PAO SPECT the patients will be followed by one of the neurologist at six weeks and three months.

Progress: This study was terminated due to lack of clinical participation by the Neurology Service since the transfer of Dr. Sinoff (previous liaison).

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-43-90 Status: Terminated

Title: Renovascular Hypertension Screening.

Start date: 27 Mar 90	Estimated completion date:
Principal Investigator: Paul A. Meese, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Radiology	Associate Investigator(s): Ronald A. Salmond, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: 19
 Periodic review date: _____ Review results: _____

Objective(s): To determine if minimally invasive screening tests can improve the detection of renovascular hypertension and provide prognostic information for revascularization procedures.

Technical Approach: Patients meeting the criteria for inclusion will be withdrawn from antihypertensive while under medical supervision. They will then have baseline and Captopril stimulated peripheral vein renin determinations, as well as a Captopril Renogram. This will be followed by baseline and Captopril renal vein renin sampling and renal arteriography. If a significant lesion is found at arteriography, a revascularization procedure will be offered. Patients undergoing revascularization will have a follow-up Captopril renogram.

Progress: Study terminated due to PCS of principal investigator.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-19-91 Status: Ongoing

Title: Changes in Hepatocyte Function Measured by Technetium TC-99M Mebrofenin.

Start date: 14 Jan 91	Estimated completion date:
Principal Investigator: Neil Katz, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Radiology/Nuclear Medicine	Associate Investigator(s): M. Oyewole Toney, LTC, MC Allan Parker, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 45
 Total number of subjects enrolled to date: 45
 Periodic review date: Review results:

Objective(s): To examine the prognostic and diagnostic role of radiopharmaceutical imaging to determine changes in hepatocyte blood flow and function over time in patients with document liver disease.

Technical Approach: Patients will undergo hepatobiliary scanning using 4-8 mCi Technetium TC-99m mebrofenin, a radiopharmaceutical currently used for hepatobiliary scanning for the assessment of acute cholecystitis. Time activity curves, which graphically depict radiopharmaceutical uptake and excretion will be generated for the imaging period of one hour.

Progress: Developed liver function index (LFI) and compared to albumin level, bilirubin and protime prolongation, as well as Pugh classification.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-26-91 Status: Ongoing

Title: Evaluation of Bone Density Measurement of Young Adults with and without Stress Fractures.

Start date: 6 Feb 91	Estimated completion date:
Principal Investigator: Rhonda W. Wyatt, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Radiology/Nuclear Medicine	Associate Investigator(s): M. Oyewole Toney, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 62
 Total number of subjects enrolled to date: 62
 Periodic review date: _____ Review results: _____

Objective(s): To determine if bone density measurements correlate with presence of stress fractures.

Technical Approach: Bone scans are performed to determine if the patients has a stress fracture of the lower extremities and pelvis. The bone mineral density of each patient's lumbar spine, proximal femur, and forearm are obtained using dual photon absorbtometry. The bone mineral density (BMD) of patients without stress fractures is then compared with the BMD of patients with stress fractures.

Progress: Abstract presented at Texas Medical Association and Southwest Chapter Society of Nuclear Medicine Annual Meeting. NOTE: LTC Wyatt has been transferred to Travis Air Force Base.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-10 Status: Ongoing

Title: The Effects of Oral Glucose Solutions on Gastric Emptying

Start date:	Estimated completion date:
Principal Investigator: LTC M. Oyewole Toney, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Radiology/Nuclear Medicine	Associate Investigator(s): MAJ Neil Katz, MC
Key Words: Gastric Emptying Glucose Solutions	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To determine the role of a new hyperosmolar glucose solution in studying gastric emptying, and to determine initial normal values for our institution.

Technical Approach: Preliminary study would compare gastric emptying rates using our standard solid and liquid agents (eggs, and water, respectively), as well as a hyperosmolar glucose solution developed by Phillips, et al.

Progress: Study completed. No further patients being done. Data being used internally.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-89 Status: Ongoing

Title: Comparison of Film Screen Radiography, Computed Radiography, and Kodak Insight Filmscreen in Demonstrating Mediastinal Anatomy

Start date: 5 Oct 92	Estimated completion date: 15 Jun 93
Principal Investigator: CPT Timothy J. Cramer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Radiology	Associate Investigator(s): COL Anna K. Chacko, MC COL Michael D. Redwine, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 170
 Total number of subjects enrolled to date: 170
 Periodic review date: Review results:

Objective(s): To compare the efficacy of conventional film screen radiography with computed radiography and the Kodak Insight Screen/film system in the evaluation of mediastinal anatomy and definition of five mediastinal lines in adult patients. The anatomic lines and stripes to be evaluated include the right paratracheal stripe, the right esophagopleural strips, the left paraspinal line, the right paraspinal line, and the aorticopulmonary stripe.

Technical Approach: Study will compare the ability of three radiographic methods to demonstrate mediastinal anatomy.

Progress: Currently, 170 of 285 patients have been enrolled in the study. Preliminary results suggest our visualization of mediastinal lines on the standard filmscreen is equivalent to previously reported findings of Heitzman and Felson. The demonstration of mediastinal anatomy on the Kodak Insight and Fuji Digital systems are roughly equal to this point. There may be some improvement over more recent data obtained by Woodring et al., in their study using Kodak Ortho C film and a low reflection, double emulsion system.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-50-87 Status: Ongoing

Title: Chromosomal Analysis of Genitourinary Neoplasms.

Start date: 11 May 87	Estimated completion date:
Principal Investigator: Ian M. Thompson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Urology	Associate Investigator(s): Eric J. Zeidman, MAJ, MC Kurt L. Hansberry, CPT, MC Isidoro Chapa GS-7
Key Words: Karyotype	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$20,726.31

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: n/a Review results: _____

Objective(s): To correlate tumor karyotypes with patient data, tumor stage and grade, and clinical course of the disease.

Technical Approach: At the time of removal of a genitourinary tumor, a small piece of tumor tissue is sent for karyotyping. The technique for karyotyping The technique for karyotyping employs the coverslip method. Chromosomal banding includes standard techniques for G-banding, Q-banding (fluorescence), and C-banding. Photographs include intact banded metaphase plates. Karyotyping will be according to standard nomenclature.

Progress: Several characteristic changes have been observed with karyotypic analysis of GU neoplasms, most notably carcinoma of the prostate. In specimen obtained from radical prostatectomy specimens, several have demonstrated partial deletion of the long arm of the #12 chromosome. At the present time, a complete re-evaluation of all of the patients in the database is ongoing. An attempt will be made to correlate the clinical course of the tumor (stage, grade, time to progression, time to metastases, and time to death) with the karyotypic changes. It is anticipated that this review will be completed by 30 December 1991. At that time, the protocol will be reevaluated and consideration given to proceed as-is, changing the focus, or terminating the protocol.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-90-87 Status: Ongoing

Title: Opti-Fix™ Hip Prosthesis (Multicenter Study).

Start date: 21 Sep 87	Estimated completion date:
Principal Investigator: Allen L. Bucknell, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Orthopedics	Associate Investigator(s):
Key Words: Prosthesis, hip	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
 Total number of subjects enrolled to date: 10
 Periodic review date: 21 Oct 91 Review results: Continue

Objective(s): To prove safety and efficacy of the use of porous surfaces (with stability afforded by biologic fixation instead of bone cement) by statistical comparison to similar patient populations of like cemented components and other published data.

Technical Approach: Patients requiring total hip replacement will be asked to participate in this study. If they agree, the Opti-Fix™ will be implanted as outlined in the study protocol.

Progress: Five year stability demonstrated. Thigh pain rate is 2%. Study (observation, periodic).

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-79-88 Status: Ongoing

Title: Collaborative Ocular Melanoma Study.

Start date: 8 Sep 88	Estimated completion date: 1998
Principal Investigator: Donald A. Hollsten, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Ophthalmology	Associate Investigator(s): William L. White, MAJ, MC
Key Words: Melanoma	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
 Total number of subjects enrolled to date: 1
 Periodic review date: 16 Sep 91 Review results: Continue

Objective(s): 1) To determine the efficacy of enucleation versus plaque irradiation in the treatment of medium size ocular melanomas.

2) To determine the efficacy of enucleation without pre-operative external radiation versus enucleation combined with pre-operative external radiation in the treatment of large ocular melanomas.

3) To determine the clinical course and community treatment standards in the treatment of small ocular melanomas.

Technical Approach: As outlined in the Collaborative Group protocol. The principal investigator will serve as the enucleating surgeon on this study.

Progress: One patient was enrolled through Brooke Army Medical Center into the Collaborative Ocular Melanoma Study during this reporting period. It is important to note that BAMC is a sub-center of a nationwide multi-center study looking at the response of chordal melanomas to various treatment modalities. It is anticipated that enrollment of patients at Brooke Army Medical Center will be low as this is a very unusual condition. This study will be ongoing until the mid-late 90's to ensure that an adequate number of patients are enrolled and followed for an adequate period of time.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-2-89 Status: Ongoing

Title: Incidence of Asymptomatic Varicocele in Fertile Man

Start date: 22 Nov 89	Estimated completion date:
Principal Investigator: Ian M. Thompson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Urology	Associate Investigator(s): Eric J. Zeidman, LTC, MC Edmund Sabanegh, MAJ, MC (USAF) Edmund Sabanegh, MAJ, MC Francisco R. Rodríguez, COL, MC
Key Words: Varicocele	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
 Total number of subjects enrolled to date: 0
 Periodic review date: n/a Review results: _____

Objective(s): To determine the incidence of asymptomatic varicocele in a group of men with proven fertility.

Technical Approach: All men requesting bilateral scrotal vas ligation for contraception will be eligible for inclusion. Patient will undergo vasectomy in a routine fashion. Prior to vasectomy, Doppler examination will be performed of the left and right spermatic cords. Patients will be first examined recumbent during comfortable respirations. Then they will be asked to perform a valsalva maneuver, and if a venous whir is detected, will be designated as possessing varicocele by this test. Following venous Doppler, scrotal ultrasound will be performed. If, on valsalva, scrotal ultrasound detects veins within the spermatic cord of 3 mm or greater, a ultrasound-detected varicocele will be scored. Immediately prior to vasectomy, standard semen analysis will be performed to quantitate semen motility, morphology, and total count.

Progress: A total of 13 patients from BAMC have been studied. To these have been included 18 patients of Dr. Bishop of WBAMC. These initial patients have been found to have a 29% of subclinical palpable varicocele and an additional 19% with varicocele noted with Doppler and/or ultrasound. of vasectomy patients will provide an easier method for patients counseling and for protocol completion.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-16-89 Status: Completed

Title: Argon Laser Photocoagulation in the Treatment of Pseudophakic Cystoid Macular Edema.

Start date: 20 Dec 88	Estimated completion date:
Principal Investigator: Susan L. Parks, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Ophthalmology	Associate Investigator(s): Calvin E. Mein, COL, MC
Key Words: Laser, argon photocoagulation Cystoid macular edema	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
 Total number of subjects enrolled to date: 6
 Periodic review date: 25 Feb 91 Review results: Continue

Objective(s): To compare observation vs argon laser photocoagulation in the treatment of pseudophakic cystoid macular edema (CMS).

Technical Approach: Fifty patients will be selected who have had CME for greater than six months and have vision worse than 20/40. The patients will be randomly assigned to treatment for observation. Vision, photos, and fluorescein angiograms will be taken on each patient. Both groups will be followed at periodic intervals for up to two years in which vision will be retested and fluorescein angiograms repeated. Improvement in vision in the treatment group will be seen as a positive result having the use of laser photocoagulation in aphakic CME.

Progress: Six patients have been enrolled, four were treated and two observed. One observed got better. Of the four treated, two improved significantly. No further enrollment has been performed and follow-up of these patients has not altered the initial results. The results of this study were reported at the Alamo City Resident's Conference held in Spring 1991.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-115-89 Status: Ongoing

Title: Treatment of Metastatic Renal Cell Carcinoma with Cimetidine: A Phase II Trial.

Start date: 8 Sep 89	Estimated completion date:
Principal Investigator: Ian M. Thompson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Urology	Associate Investigator(s): Arlene J. Zaloznik, LTC, MC M. Ernest Marshall, M.D.
Key Words:	
Accumulative MEDCASE Cost:	Estimated Accumulative OMA Cost:
Number of subjects enrolled during reporting period: <u>1</u>	
Total number of subjects enrolled to date: <u>4</u>	
Periodic review date: <u>16 Sep 91</u> Review results: <u>Continue</u>	

Objective(s): 1) To evaluate the likelihood of response in order to assess whether this regimen should be advanced to further studies.

2) To evaluate and qualitative and quantitative toxicities of this regimen administered in a phase II study.

Technical Approach: All patients will receive cimetidine, 400 mg orally four times daily. There will be no dose reduction or escalation within this trial. Patients experiencing significant CNS toxicity will be removed from study. Any other toxicities requiring cessation of therapy will be documented.

Progress: Since 1991, one additional patient has entered the study. At this time, there are four patients on-study. One patient with metastatic renal cell carcinoma has had a partial response and is now with stable disease over three years following diagnosis. He has an excellent performance status and is continuing his normal lifestyle. An additional patient with metastatic disease is stable with an excellent performance status 6 months following treatment initiation. There have been no adverse sequelae of the use of cimetidine. The study will remain open for patient accrual as there are many patients who live remotely from medical center care for which such a non-toxic therapeutic modality allows them to remain in their home/community free from the toxicity associated with most current aggressive therapies for metastatic renal cell carcinoma.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-127-89 Status: Ongoing

Title: A Randomized Prospective Study of Lumbar Spinal Fusions with and without Transpedicular Screw-Plate Fixation.

Start date: 31 Oct 89	Estimated completion date:
Principal Investigator: Jeffrey D. Coe, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Orthopedic	Associate Investigator(s): William C. Lauerman, MAJ, USAF, MC James E. Cain, MAJ, USAF, MC Kevin P. Murphy, CPT, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4
 Total number of subjects enrolled to date: 18
 Periodic review date: 10 Sep 90 Review results: Continue

Objective(s): To compare the results of spinal fusion with and without the use of transpedicular instrumentation in the lumbar spine.

Technical Approach: In a multi-center study to be performed by the Orthopaedic Surgery Services of the Joint Military Medical Commander of San Antonio, a randomized prospective study will be performed in patients undergoing lumbar spinal fusions. The study group will undergo transpedicular instrumentation with Steffee (VSP) bone plates and screws and the control group will undergo fusion without instrumentation. A total of 100 patients will be entered into the study (approximately 30 to 40 at BAMC). The primary goal of the study is to determine if there is a difference in subjective pain relief, fusion rates, and complication rates between the study group (instrumented and fused) and the control group (instrumented and fused).

Progress: No report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-8-90 Status: Ongoing

Title: Clinical Evaluation of Collagen/Chlorhexidine (VitaPatch) Surgical Dressing and Traction Pin Badge.

Start date: 7 Dec 89	Estimated completion date:
Principal Investigator: Allan L. Bucknell, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Orthopaedic	Associate Investigator(s): Daryl W. Peterson, CPT, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 50
 Total number of subjects enrolled to date: 50
 Periodic review date: 25 Feb 91 Review results: Continue

Objective(s): To evaluate the safety and effectiveness of a new pin protection device called VitaPatch™. The effectiveness of VitaPatch will be evaluated in terms of differences in the rate of bacterial colonization/infection, site appearance, convenience of use, and patient comfort as compared with established protocol.

Technical Approach: All patients over the age of 18 who have fresh fractures treated with external fixation devices will be eligible for the study. Prospective patients are evaluated at the request of the primary physician, and a determination for inclusion made by the primary investigators. Each patient will serve as his/her own control with the same number of pins used as controls as the number of pins testing VitaPatch. Control VitaPatch test pins are to be alternated so that no bias is introduced.

Progress: Fifty patients enrolled. Bacteriologic studies are being statistically analyzed. Preliminary data analysis suggest marked effectiveness.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-18-90 Status: Completed

Title: A Randomized Prospective Clinical Trial of Vitrectomy in the Management of Idiopathic Macular Holes.

Start date: 18 Jan 90	Estimated completion date:
Principal Investigator: Dwight W. Wood, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Ophthalmology	Associate Investigator(s): Calvin E. Mein, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: 0	
Total number of subjects enrolled to date: 9	
Periodic review date: Review results:	

Objective(s): The goal of this study is to determine if core vitrectomy with posterior hyaloid membrane peeling and gas fluid exchange is of benefit in restoring visual loss due to macular hole.

Technical Approach: Comparison of the rates of visual recovery, macular hole resolution, and operative complications occurring prospectively in 40 patients with idiopathic macular holes who are randomized to 1) an untreated control group or 2) a study group undergoing vitrectomy will be made.

Progress: This study is complete. It was found during the follow-up of patients enrolled in the study that there was a statistically significant increase in the progression of cataracts affecting visual acuity in those patients who underwent vitrectomy for idiopathic macular holes. As patients with idiopathic macular holes have profoundly affective central visual acuity, the cataract progression was not such to affect individuals' lifestyles, but was noted in following these patients.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-19-90 Status: Terminated

Title: Effect of Mini-Dose Fentanyl on Subarachnoid Anesthesia with Isobaric Lidocaine.

Start date: 18 Jan 90	Estimated completion date:
Principal Investigator: Douglas Chapman, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/ Anesthesiology	Associate Investigator(s): R.K. Baumgarten, LTC, MC K. Kenworthy, CPT, MC
Key Words: Subarachnoid Block Fentanyl, Narcotic	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 20
 Total number of subjects enrolled to date: 20
 Periodic review date: Review results:

Objective(s): The purpose of this randomized, double-blind study is to determine if the addition of mini-dose fentanyl (10 mcg) improves the quality of spinal anesthesia produced by isobaric lidocaine (80 mg).

Technical Approach: Patients who request spinal anesthesia for lower extremity orthopaedic procedures and lower abdominal surgery will be eligible for this study. A total of 100 patients will be studied (control + treatment groups). All blocks will be placed in the sitting position utilizing a midline approach L3-4 with a #25 needle. The control group will receive 4 ml of 2% lidocaine plus 0.2 ml normal saline. The treatment group will receive 4 ml of 2% lidocaine plus 0.2 ml fentanyl. Quality of analgesia will be assessed using the following parameters: 1) level of pinprick at 10, 20, 30 and 60 minutes, 2) patient complains of pain of incision or tourniquet pain, 3) dosage of supplementary analgesics intraoperatively and in the recovery room. Occurrence of nausea, vomiting or pruritus will be recorded.

Progress: Study currently is not being done. We are awaiting the initial results of another study on Isobaric Lidocaine. That study is looking at the effect of the temperature of the solution, which this study doesn't control for.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-32-90 Status: Ongoing

Title: Intravenous Injection of Prostaglandin E1 for Erectile Impotency.

Start date: 13 Feb 90	Estimated completion date:
Principal Investigator: Ramón L. Caballero, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Urology Service	Associate Investigator(s): Ian M. Thompson, MAJ, MC
Key Words: Impotency, Erectile	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: 17	
Total number of subjects enrolled to date: 18	
Periodic review date: 20 May 91 Review results: Continue	

Objective(s): To determine the benefit of intravenous penile injection of prostaglandin E1 in patients with erectile impotency.

Technical Approach: Patients will complete a questionnaire, undergo a full genital exam and battery of blood tests at the beginning of the study, Part 1 of the study will involve in office, physician supervised injections into the penile bodies at weekly intervals until an adequate dose is reached not exceeding a maximum predetermined dose. Part 2 will involve home self-injections in patients who are successful in phase 1.

Progress: Of the 10 patients who completed phase 1, 8 have required maximum dose of 20 mcg and 2 have required minimum dose of 10 mcg with two of these injecting with dose of 7 mcg (self titrated at home by the end of the study since erections were of longer duration than needed). This data suggests that a dose of 15 mcg may be unnecessary. One of the patients responding to 10 mcg had a 3.5 hr. erection despite masturbation and since painful was categorized as priapism. He had reversal of priapism at ER, approximately 4 hrs. after onset with full resolution with injection of dilute epinephrine. He was subsequently injected with 5 mcg with a 3 hr. erection that subsided after masturbation confirming no long term sequelae.

Of the remaining 9 patients that are self injecting at home, 8 are still injecting with erections good enough for adequate intercourse. The remaining patient did not meet Rigiscan criteria for a good erection during phase one but insisted on self-injecting and thus tried the injections at home with unsatisfactory results secondary to poor erections. He has elected for a penile prosthesis. Also note that of the 8 patients that are still injecting, 3 also did not meet Rigiscan criteria for a good erection but are happy on self injection therapy avoiding need for a penile prosthesis.

Aside from the aforementioned episode of priapism, no evidence of other complications such as nodules or plaques are noted at this time. The baseline post study Rigiscan date is not ready for analysis at the present time.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-38-90 Status: Completed

Title: The Effect of Rapid Sequence Induction of Anesthesia on Intraocular Pressure.

Start date: 12 Mar 90	Estimated completion date:
Principal Investigator: Thaddeus J. Krolicki, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Ophthalmology	Associate Investigator(s): Stephen Gates, CPT, MC Calvin E. Mein, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
 Total number of subjects enrolled to date: 9
 Periodic review date: 20 May 91 Review results: Continue

Objective(s): This study is designed to help resolve current conflicts between the ophthalmologic and anesthesia literature regarding optimal anesthetic techniques for the induction of general anesthesia in non-fasting patients with perforating ocular trauma. We propose to study the effect on IOP of a widely accepted rapid sequence induction regimen consisting of succinylcholine, lidocaine, fentanyl, curare, and sodium thiopental.

Technical Approach: We propose to study the combined effect of succinylcholine, curare, lidocaine, fentanyl, and sodium thiopental on IOP in a group of 30 normal patients undergoing general anesthesia. We will compare each subject's preoperative IOP, obtained using a hand-held Perkins tonometer, with their IOP's measured during the first 5 minutes of induction.

Progress: This research project has been completed and closed. It was determined that there was not a statistically significant rise in intraocular pressure during the rapid sequence induction of anesthesia. The results of this were reported at the Alamo City Residents Conference in Spring 1992.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-53-90 Status: Ongoing

Title: A Comparison of Arterial Oxygen Partial Pressure Achieved with Intermittent Flow Oxygen (IF) from Demand Controller and Continuous Flow Oxygen (CF).

Start date: 3 Apr 89	Estimated completion date:
Principal Investigator: Charles P. Kingsley, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Anesthesiology	Associate Investigator(s): Joseph P. Ducey, MAJ, MC William Strong, CPT, MC Linda Strezlecki, LTC, AN
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: 16
 Periodic review date: 20 May 91 Review results: _____

Objective(s): Animal studies and human studies in chronically ill patients have shown that intermittent flow oxygen delivered by a demand oxygen controller (DOC) maintains arterial oxygen tensions at values that are equal to those values with continuous flow oxygen (CF). Twenty five postoperative patients for pulmonary surgery will be studied in a randomized crossover design.

Technical Approach: Twenty five adult patients schedule for pulmonary surgery requiring routine arterial catheter placement and postoperative intensive care admission will be enrolled in the study. A randomized crossover design with each patient serving as his own control will be employed to evaluate the arterial oxygen partial pressures achieved with intermittent oxygen therapy from a demand oxygen controller compared to continuous flow oxygen at comparable flow rates. Arterial blood gases will be draw at 30 minute intervals, and total oxygen use will be recorded. Continuous pulse oximetry will insure adequate oxygen delivery.

Progress: Data is being analyzed by USABDRL (report pending).

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-61-90 Status: Ongoing

Title: Swimming and Myringotomy Tubes.

Start date: 12 May 90	Estimated completion date:
Principal Investigator: Kweon I. Stambaugh, LTC, MC	Facility: Brooke Army Medical Center
Department/Service: Department Surgery/Otorhinolaryngology	Associate Investigator(s): Jeffrey Braaten, CPT, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 100
 Total number of subjects enrolled to date: 160
 Periodic review date: Oct 92 Review results: Continue

Objective(s): To determine the incidence of ear infection while swimming with middle ear ventilation tubes.

Technical Approach: All patients undergoing myringotomy and insertion of ventilation tubes that are intact and patent during the swimming season, June thru September, will be included in the study. Swimmers and non-swimmers will be randomized by a table of random numbers. A variety of ventilation tubes will be placed based on the surgeons personal preference. Patients will be seen routinely two weeks postoperatively and then every three months thereafter until the tubes are extruded. Patients will be given a calendar and questionnaire. The days swimming, the number of ear infections, and their relationship to an upper respiratory infection will be recorded.

Progress: Approximately 160 patients have been enrolled as of the end of last summer. We anticipate having accurate numbers by the end of the next summer season. No significant results to report but the trend seems to show that swimming has no real adversity on patients who have PG tubes.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-66-90 Status: Terminated

Title: Does Nitroglycerin Infusion Decrease the Incidence of Pre-Cardiopulmonary Bypass Myocardial Ischemia?

Start date: 15 May 90	Estimated completion date:
Principal Investigator: Paul D. Mongan, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Anesthesiology	Associate Investigator(s): Michael Hosking, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: _____	
Total number of subjects enrolled to date: <u>3</u>	
Periodic review date: _____ Review results: _____	

Objective(s): 1) To determine the incidence of pre-CPB myocardial ischemia as diagnosed by transesophageal electrocardiogram (TEE). 2) To evaluate if prophylactic IV nitroglycerin infusion at a rate of 1 mcg/kg/min provides effective prophylaxis for pre-CPB myocardial ischemia which is unrelated to indices of oxygen demand. 3) To compare IV NTG with a control infusion of physiologic saline 4) To evaluate if changes in hemodynamic variables (HR +/-10%, BP +/-20%) affects the incidence of pre-CPB ischemia. 5) To evaluate if pre-CPB ischemia is an independent predictor of postoperative cardiac morbidity.

Technical Approach: This is a prospective blinded study which will be conducted on 120 patients randomized into two groups. Group I will receive an infusion of physiologic saline and group II will receive an infusion of IV NTG at a rate of 1 mc/kg/min. This population size provides for a power of .8 and $p < .05$ if pre-CPB myocardial ischemia is reduced by 20%.

Progress: Study terminated secondary to other investigators publishing of a similar study.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-76-90 Status: Terminated

Title: Analysis of Mesenteric Venous Blood for Malignant Cells in the Presence of Tumor Manipulation in Colon Cancer.

Start date: 19 Jun 90	Estimated completion date:
Principal Investigator: (vice Robertson) Audrey Narducci, CPT	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/General Surgery	Associate Investigator(s): Janice Grassel
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3
 Total number of subjects enrolled to date: 10
 Periodic review date: Review results:

Objective(s): To determine of intraoperative tumor manipulation in shedding of malignant cells into the mesenteric venous blood in patients with adenocarcinoma of the colon.

Technical Approach: In the operating room, the proximal and distal portion of the segment of colon to be removed will be divided. The mesentery will be taken down with the exception of the primary feeding artery and draining vein. The vein will then be divided and a sample of blood obtained. The tumor will be Compressed gently in a controlled, reproducible manner and a second sample of blood will be obtained. This blood will be analyzed for the presence or absence of tumor cells. Conventional staining techniques and flow cytometry using a cancer specific monoclonal antibody will be used.

Progress: No report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-91-90 Status: Ongoing

Title: The Incidence of Prostatism in Older Males Presenting for Herniorrhaphy.

Start date: 30 Aug 90	Estimated completion date:
Principal Investigator: Kevin Shandera, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Ian M. Thompson, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 78
 Total number of subjects enrolled to date: 78
 Periodic review date: _____ Review results: _____

Objective(s): To determine the incidence of prostatism in males 40 years of age and older who present for herniorrhaphy.

Technical Approach: One hundred consecutive men scheduled for herniorrhaphy will undergo urodynamics evaluation in an attempt to detect asymptomatic or minimally symptomatic physiologically-significant bladder outlet obstruction secondary to prostatic hyperplasia. Should such obstruction be encountered, Urology consultation would be requested before herniorrhaphy is undertaken.

Progress: No report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-94-90 Status: Terminated

Title: Protein Turnover, Pulmonary Amino Acid Flux, and Nitrogen Balance in Critically Ill Surgical Patients.

Start date: 31 Aug 90	Estimated completion date:
Principal Investigator: David W. Mozingo, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/SICU	Associate Investigator(s): William K. Becker, LTC, MC James M. Lamiell, LTC, MC R. Bernard Rochon, MAJ, MC Glen E. Gueller, SFC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
 Total number of subjects enrolled to date: 8
 Periodic review date: _____ Review results: _____

Objective(s): To measure protein turnover, amino acid flux, and nitrogen balance across the lungs in critically ill surgical patients.

Technical Approach: To measure how the lung can change amino acids, glycine will be infused. Before, during, and after the infusion blood will be drawn. Samples of urine will be obtained for analysis.

Progress: A statistically significant increase in the release of glycine, lysine, glutamine and glutamate by the lung was demonstrated in burn patients compared to control patients. For all 20 amino acids the trend appeared to be that, compared to control patients, general surgery patients have increased amino acid pulmonary flux and burn patients have an even greater amino acid release. More patients will be required to reach statistical significance of this trend. The protocol should be terminated at this time. The objectives were met with the number of patients studied. Further human studies should follow basic laboratory studies pertaining to the mechanism and clinical significance of our findings. A summary is attached. NOTE: The five burn patients were studied under a separate R&D protocol.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-95-90 Status: Ongoing

Title: Effect of the Use of Perioperative Antibiotics on the Incidence of Wound Infection Following Mastectomy.

Start date: 1 Aug 89	Estimated completion date:
Principal Investigator: Steven B. Olsen, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/General Surgery	Associate Investigator(s): Daniel P. Otchy, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 31
 Total number of subjects enrolled to date: 38
 Periodic review date: Review results: Continue

Objective(s): To prospectively analyze the effect of perioperative antibiotic use on the incidence of wound infection following mastectomy.

Technical Approach: This subject population will include all females who present to the General Surgery Service from August 1989 to December 1990. The subjects will be randomized to one of two double-blinded groups: the first group will received intravenous antibiotics in a standard perioperative regimen consisting of a dose preoperatively and postoperative doses for 24 hours postoperatively, and the second group will receive intravenous doses of saline at the same times when antibiotic would normally be administered. The incidence of wound infections and other infective complications will be monitored during the hospital stay and at follow-up visits.

Progress: No report provided by principal investigator.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-97-90 Status: Completed

Title: A 16 Week Double Blind Placebo-Controlled Dose-Response Study Using Doxazosin Tablets for the Treatment of Benign Prostatic Hyperplasia in Patients With Mild to Moderate Essential Hypertension.

Start date: 7 Sep 90	Estimated completion date:
Principal Investigator: Ian M. Thompson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Eric S. Zeidman, LTC, MC Joseph P. Johns, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
 Total number of subjects enrolled to date: 51
 Periodic review date: 19 Nov 92 Review results: Continue

Objective(s): 1) To determine the safety and efficacy of doxazosin tablets in the treatment of patients with benign prostatic hyperplasia and mild to moderate essential hypertension.
 2) To determine if there are any changes in symptomatology and urodynamic variables related to dose and duration of therapy.

Technical Approach: The study is designed as a double-blind, placebo-controlled, parallel-trial with five treatment groups: placebo and four different doses of doxazosin (2, 4, 8 and 12 mg). This study will be divided into four phases lasting a total of 16 weeks: Phase I (Screening), minimum of one week; Phase II (placebo), two weeks; Phase III (titration), five weeks and Phase IV (efficacy), nine weeks. All medications are to be taken in the morning. After all evaluations for a given visit have been completed, the patient will be dosed from the next week's medication card.

Progress: This study is now completed and closed.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-98-90 Status: Ongoing

Title: An Open Label Extension Study Using Doxazosin Tablets for the Treatment of Benign Prostatic Hyperplasia in Patients with Mild to Moderate Essential Hypertension.

Start date: 7 Sep 90	Estimated completion date:
Principal Investigator: Ian M. Thompson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Eric S. Zeidman, LTC, MC Paul Desmond, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
 Total number of subjects enrolled to date: 6
 Periodic review date: 19 Nov 92 Review results: Continue

Objective(s): 1) To determine the long-term safety and efficacy of doxazosin tablets in hypertensive patients with benign prostatic hyperplasia (BPH).
 2) To obtain information regarding the optimal dose of doxazosin tablets required on a long-term basis for patients with BPH.
 Technical Approach: Patients who successfully complete the 16 week (double blind study may enter the open label extension study. They must do so within one week. Patients who withdrew from the 16 week study, after randomization, due to adverse experiences or lack of efficacy may also enter. The study is designated as an open-label, long-term, follow-up trial to the initial 16 week study. All patients in the open label trial will initially receive 1 mg of doxazosin daily and will be titrated upward at two week intervals, one dose level at a time, to a daily dose of 2, 4, 8, or 12 mg. A patient's upward titration will be dependent upon their adverse experiences, blood pressure response and BPH symptomatology. Once an optimal dose is achieved, it will be maintained unless the investigator determines that an adjustment in dose (lower or higher) is medically indicated.
 Progress: This study extends on an open-label basis the use of doxazosin to previously randomized patients on the 16-week placebo-controlled dose-response study with this agent. To date, five patients have enrolled, and all are experiencing benefits of this agent. All patients with acceptable blood pressure and urinary symptom improvement with this agent will be kept at the dose achieved and periodically re-evaluated for patient satisfaction and blood pressure control. Enrollment is closed, but the 6 enrolled patients are all experiencing benefits of this agent.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-101-90 Status: Completed

Title: Clinical Study of the Surgitek Prostate Balloon Dilatation Catheter for Use in Males with Benign Prostatic Hyperplasia.

Start date: 13 Sep 90	Estimated completion date: 31 Dec 92
Principal Investigator: Ian Thompson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Eric S. Zeidman, LTC, MC Paul Desmond, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2
Total number of subjects enrolled to date: 27
Periodic review date: 19 Nov 92 Review results: Ongoing

Objective(s): To evaluate the safety and effectiveness of the SURGITEK[®] Prostate Balloon Dilatation Catheter in treating men with benign prostatic hyperplasia.

Technical Approach: Adult males age 18 years and over will comprise the study group. Up to 81 subjects with symptomatic benign prostatic hyperplasia will be included in the study. Following local anesthesia, the appropriate size balloon catheter will be positioned and the balloon inflated with sterile water and maintained at a recommended pressure for approximately 10-15 minutes. When the amount of dilatation desired is completed, the dilatation catheter will be deflated and removed.

Progress: The study is scheduled for completion on 31 December 92. A total of 27 patients have been entered into the study with all except 2 patients now evaluable at the one year mark. Patients will continue to be followed by the Urology Service for data management. The study will close at the end of the calendar year.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-102-90 Status: Completed

Title: Treatment of Bladder Carcinoma (T₁-T₂ and CIS) with Intravesical Interleukin-2 (Cetus): Phase II.

Start date: 13 Sep 90	Estimated completion date:
Principal Investigator: Ian M. Thompson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Eric S. Zeidman, LTC, MC Paul Desmond, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
 Total number of subjects enrolled to date: 1
 Periodic review date: 19 Nov 92 Review results: Continue

Objective(s): 1) To determine the effectiveness (response rate) of intravesicular IL-2 in the treatment of bladder carcinoma stages T₁-T₂ and carcinoma in situ (CIS).

2) To determine the toxicity of intravesicular IL-2 in such patients.

Technical Approach: Patients must have histologically proven primary bladder carcinoma (any grade). Patients are eligible if they have any of the following stages: (a) recurrent stage T₁ or T₂; (b) multiple tumors (> 3) at presentation (c) a primary tumor > 3 cm regardless of depth of invasion; (d) T₂; (e) T₂; (f) carcinoma in situ. Therapy will follow the schema outlined in the study protocol.

Progress: The one patient on study tolerated the treatments without toxicity but following treatment, as before with all prior intravesical therapies, had persistent carcinoma in situ and subsequently underwent radical cystectomy and has recovered well. This study is now closed.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-1-91 Status: Ongoing

Title: Use of a Foot compression Pump in the Prevention of Deep Vein Thrombosis in Total Joint Replacement.

Start date: 8 Nov 89	Estimated completion date:
Principal Investigator: James P. Stannard, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Orthopaedics	Associate Investigator(s): Robert M. Harris, CPT, MC Jeffrey J. Behrens, MAJ, MC Allan L. Bucknell, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 35
Total number of subjects enrolled to date: 140
Periodic review date: Dec 92 Review results:

Objective(s): To determine the clinical usefulness of the AVI foot pump as prophylaxis for DVTs.

Technical Approach: Subjects for this study will be patients undergoing either hip replacement arthroplasty or total knee replacement arthroplasty. Patients will be randomized into one of three groups. Group A will be patients given subcutaneous heparin for the first 3 days (or until ambulatory) and then given Ecotrin as prophylaxis for DVTs. Group B will be patients given an AVI foot pump as their prophylaxis. The pump will be used at all times when the patient is in bed or in a chair. Group C will be patients given both the Heparin/Ecotrin regimen and a AVI foot pump. All patients will be evaluated for the development of DVTs via serial Duplex ultrasound screening at weekly intervals while the inpatients.

Progress: Total knee study complete 75/75. No DVT in foot pump groups. 1 DVT in controlled group. New protocol submitted for TKA and evaluation with venograms. Total hip study 70/75 hips done. 5 DVTs all in non-foot pump patients.

Funding 93. All supplies are donated to BAMC.

40/75 hips enrolled with no deep vein thromboses (vs. 4 in controls) and more rapid wound closure with foot pump.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-7-91 Status: Ongoing

Title: Prognostic Value of Static DNA Cytophotometry for Stage A1 Adenocarcinoma of the Prostrate.

Start date: 30 Sep 90	Estimated completion date:
Principal Investigator: David Bomalaski, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Wilfred Kearse, CPT, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: _____	
Total number of subjects enrolled to date: _____	
Periodic review date: _____ Review results: _____	

Objective(s): To determine if nuclear DNA content, as determined by static DNA cytomorphometry, has any prognostic value in predicting progression of disease or survival.

Technical Approach: Follow-up data on 56 patients with stage A1 adenocarcinoma the prostate has been accumulated. Paraffin embedded tissue specimens have been reviewed and the blocks chosen that contain cancer. They propose to Feulgen stain these specimens and perform static DNA analysis on these specimens. The ploidy the specimens will be compared to the clinical outcome to asses prognostic significance.

Progress: No report provided by principal investigator.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-20-91 Status: Ongoing

Title: Use of a Foot Pump on Reduction of Postoperative Pain and Swelling in Lower Extremity Injuries Requiring External Fixation.

Start date: 6 Feb 91	Estimated completion date:
Principal Investigator: Robert M. Harris, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Orthopaedics	Associate Investigator(s): James P. Stannard, CPT, MC Steve Martin, CPT, MC Allan L. Bucknell, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 18
Total number of subjects enrolled to date: 23
Periodic review date: Review results:

Objective(s): To determine the clinical effectiveness of the AVI Foot Pump in the reduction of the postoperative pain and swelling in lower extremity injuries which require external fixation.

Technical Approach: Patients receiving external fixation devices will be randomized into two groups. Both groups will receive DVT prophylaxis which includes subcutaneous heparin and Ectorin when ambulatory. Group A will receive an AVI Foot Pump which they will wear during nonambulatory hours. Group B, which will not receive the device, will receive the normal standard of care. All patients will undergo measurements of postoperative swelling of the mid thigh, and proximal and distal calf on POD 1, 2, 3, 5 and 7. Patients will also undergo subjective and objective evaluations of pain and medication requirements for pain for two weeks.

Progress: Significant decrease in swelling in all patients randomized to foot pump group. Two patients in control group had swelling to ring of ex fix and were discontinued from study group as failures-placed on foot pump with resolution of swelling in 24 degree.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-29-91 Status: Ongoing

Title: Estimation of the Maximum Rate of Oxygen Consumption - A New Approach.

Start date: 6 Feb 91	Estimated completion date:
Principal Investigator: Richard B. Hecker, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Critical Care	Associate Investigator(s): James M. Lamiell, COL, MC James Parker, CPT, MC Glen Gueller, SFC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 9

Total number of subjects enrolled to date: 17

Periodic review date: 27 Oct 92 Review results: _____

Objective(s): To estimate the maximum rate of oxygen consumption of healthy adult volunteers using a modified Harvard Step Test and compare the results with actual measured values of $\dot{V}O_{2max}$ obtained from an oxygen analyzer system.

Technical Approach: Thirty volunteers will undergo a modified Harvard Step Test. The volunteers will have heart rate monitored via standard 5 lead ECG. They will then be asked to mount a bicycle ergometer and provide a period of maximum exertion.

Progress: This study suffers from a lack of support personnel. The main laboratory technical assistant (SFC Gueller), who is also an associate investigator, has been tasked with numerous projects. SFC Queller has now retired from the U.S. Army and his future participation in this project is in question. Technical equipment for this project can be located in the Department of Clinical Investigation. The project will be continued at this time. Discussion with the other principal investigator (Dr. Parker) will be continued. Consents, data sheets, etc. are on file in the office of Dr. Hecker.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-30-91 Status: Ongoing

Title: Effects of Blood Transfusion on the Metabolic Rate as Measured by Indirect Calorimetry.

Start date: 6 Feb 91	Estimated completion date:
Principal Investigator: Joseph P. Ducey, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
 Total number of subjects enrolled to date: 0
 Periodic review date: Review results:

Objective(s): To measure, using indirect calorimetry, the effect of blood transfusion on the metabolic rate of intraoperative, postoperative and critically ill patients.

Technical Approach: The effect of blood transfusion on the metabolic rate of intraoperative, postoperative and critically ill patients will be measured by indirect calorimetry. We will also measure the concomitant effects of inotropic agents, paralyzing agents, mechanical ventilation, hypothermia, electrolyte and acid base disorders on O₂ utilization during and immediately following a blood transfusion.

Progress: No report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-33-91 Status: Terminated

Title: A Trial of Cryoperserved Human Veins.

Start date: 28 Feb 91	Estimated completion date:
Principal Investigator: James A. Ameika, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Cardiothoracic	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: _____	
Total number of subjects enrolled to date: _____	
Periodic review date: _____ Review results: _____	

Objective(s): To evaluate cryopreserved saphenous vein (or other suitable venous tissue) in order to determine the optimum preservation method and operative technique which contribute to long term patency.

Technical Approach: Patients scheduled for coronary artery bypass grafting who do not have adequate veins are eligible for this study. Cadaver cryopreserved veins obtained from Cryolife cardiovascular, Inc. will be used for the graft.

Progress: Study terminated. Principal investigator no longer at Brooke Army Medical Center.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-39-91 Status: Completed

Title: The Effects of Topical Oral Antiseptic Rinses on Bacterial Content of Saliva in Healthy Human Subjects.

Start date: 6 Mar 91	Estimated completion date: Jul 92
Principal Investigator: Luis Balbuena, Jr., MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Otolaryngology	Associate Investigator(s): Curtis L. Yeager, Ph.D., CPT, MS
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: 20
 Periodic review date: Oct 92 Review results: _____

Objective(s): To compare the bacterial contents of oral cavity saliva in health adult subjects before and after using an oral rinse of Clindamycin or normal saline.

Technical Approach: Twenty adults, males and females will be enrolled. Each subject will participate in four washings. Wash one consists of a vigorous ten second wash with 30 ml sterile saline. The saline is expectorated into the original tube and collected by the investigators. Wash two is the treatment wash. Ten subjects rinse for 10 seconds and expectorate 15 cc of Peridex, while another ten subjects rinse for 10 seconds and expectorate 20 cc of listerine. Wash two is discarded. Wash three is a ten second wash with sterile saline done one hour post-treatment. Wash four is a ten second wash with sterile saline done at four hours post-treatment. Serial dilutions of washes one, three, and four are plated on sheep blood agar and CDC anaerobic cultures and incubated overnight.

Progress: The study was completed with 20 subjects. (10 in each arm). The results demonstrated that there was significant reduction of bacterial colonies (aerobic and anaerobic) for both the one and four hour treatment with Clindamycin with no difference on the normal saline wash group. This pilot study demonstrated that a single rinse with Clinidamycin resolved the colony count at one hour and continued to reduce the counts for at least four hours. We plan to pick antiseptics in a similar manner in future studies.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-40-91 Status: Ongoing

Title: Physiologic Testing of a Chemical Warfare Agent Protective Patient Wrap.

Start date: 6 Mar 91	Estimated completion date:
Principal Investigator: Charles P. Kingsley, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s): David L. Danley, MAJ, MS Richard Hecker, CPT, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
 Total number of subjects enrolled to date: 1
 Periodic review date: 7 Oct 92 Review results: _____

Objective(s): To evaluate the ambient oxygen and carbon dioxide concentrations that are present during encapsulation in a threat agent protective patient wrap (WRAP).

Technical Approach: Twelve human volunteers will be encapsulated in a chemical agent protective patient wrap. During a three hour study period temperature, heart rate, minute ventilation and inspired and exhaled oxygen and carbon dioxide concentrations will be recorded. The effects of supplemental oxygen, air and air circulation within the wrap will be studied.

Progress: Wrap is being redesigned. Study on hold pending availability of new wraps.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-41-91 Status: Terminated

Title: Clinical Study of Surgitek[®] Female Incontinence Catheter.

Start date: 20 Mar 91	Estimated completion date:
Principal Investigator: Eric S. Zeidman, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Ian M. Thompson, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To assess the safety and efficacy of the Surgitek[®] Incontinence Catheter as an indwelling urological device.

Technical Approach: Phase I is a preliminary study in which the catheter will remain indwelling for a period of 7 to 10 days. During this phase, the patient will undergo endoscopic and urodynamic evaluation of the results of device placement. After completion of the preliminary study (of patients) two concurrent phase 2 studies will begin: the short-term and long-term studies. The short term study is intended for subjects requiring catheterization for a period of 14 to 90 days with three devices investigated for each subject. During the long-term study, patients will be evaluated who require catheterization for a minimum of 90 days. There will be a minimum of three consecutive device insertions with each device remaining indwelling for 30 to 37 days.

Progress: This study has been terminated because the manufacturer decided not to test the device at this time.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-44-91 Status: Terminated

Title: A Comparison of Epidural Steroid Injection with and without Local Anesthetic in the Management of Back Pain and Lumbosacral Radiculopathy: Is the Local Anesthetic Necessary?

Start date: 9 Apr 91	Estimated completion date:
Principal Investigator: Kevin Kenworthy, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5
 Total number of subjects enrolled to date: 5
 Periodic review date: Review results:

Objective(s): 1) To compare in a single-blind randomized, prospective manner the therapeutic effectiveness of epidural injections using Depomedrol with sterile normal saline or Depomedrol with 0.25% Bupivacaine.
 2) To compare the pain of epidural injection of Depomedrol with sterile normal saline to that of Depomedrol with Bupivacaine.
 3) To compare the side effects of epidural injections of epidural Depomedrol with sterile normal saline to that of Depomedrol with Bupivacaine.

Technical Approach: Patients selected by coin toss to one of two groups in a single blind manner to either receive 10 mg Depomedrol with Marcaine or normal saline. Blood pressure visual analogue scale and patients comments will be recorded at various periods of time.

Progress: Study terminated. Principal investigator no longer at Brooke Army Medical Center.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-47-91 Status: Terminated

Title: Comparison of Recovery Time Following Anesthesia.

Start date: 2 May 91	Estimated completion date:
Principal Investigator: Jack C. Chavez, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s): Gary Welch, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): Using an electronic game which requires strategy as well as eye-hand coordination we will compare pre-anesthetic with post-anesthetic performance following induction of one of two standard agents - propofol or pentothal.

Technical Approach: Healthy women (ASA I,II) undergoing laparoscopic tubal ligation and healthy patients of both sexes having oral surgery in the oral surgery clinic will be the study population. Preoperative scores (after the trials) will be compared to postoperative scores at 5, 15, and 30 minutes.

Progress: The study was cancelled prior to starting when it was discovered that repeated attempts at game playing would increase the patients score and this could not be controlled.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-48-91 Status: Ongoing

Title: A Comparison of Postoperative Sore Throat in Patients Who Receive Succinylcholine or Vecuronium for Endotracheal Intubation.

Start date: 2 May 91	Estimated completion date:
Principal Investigator: Donald B. Tallackson, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service:	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 45

Total number of subjects enrolled to date: 50

Periodic review date: _____ Review results: _____

Objective(s): To determine whether the administration of succinylcholine to facilitate endotracheal intubation increases postoperative sore throat when compared to vecuronium administration.

Technical Approach: Eighty women undergoing intra-abdominal procedures will be randomized to receive succinylcholine or vecuronium at the time of endotracheal intubation. Anesthesia will be standardized and variables known to affect sore throat will be controlled. Patients will be interviewed postoperatively to determine severity and incidence of sore throat and hoarseness.

Progress: Forty-five patients have been entered thus far, however the randomized code has not been broken yet. Therefore, no results are currently available. No unexpected complications have arisen in the study.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-50-91 Status: Ongoing

Title: Comparison of Trigger Point Injections Using Kerolac Tromethamine versus Saline in the Treatment of Myofacial Pain Syndrome.

Start date: 2 May 91	Estimated completion date:
Principal Investigator: Roger L. Wesley, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s): William Strong, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6
 Total number of subjects enrolled to date: 6
 Periodic review date: _____ Review results: _____

Objective(s): To determine if kerolac tromethamine is effective in providing pain relief in myofascial pain syndrome, and if so, for how long.

Technical Approach: Fifty adult volunteers who are referred to the pain clinic with myofascial pain syndrome will be enrolled in the double blinded, randomized study. Pain intensity and quality will be assessed using pressure algometry all visual analog pain scales. Patients will then be given trigger point injection with either ketorolac tromethamine or saline in a double blinded fashion. Pain reassessment will be done at 10 minutes, 6 hours, 1 day and 1 week following injection.

Progress: Principal investigator has no definitive data to report.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-53-91 Status: Terminated

Title: Follow-up Magnetic Image Evaluation of Bone-Tendon-Bone Anterior Cruciate Ligament Grafts.

Start date:	Estimated completion date:
Principal Investigator: Doug A. Vermillion, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Orthopaedics	Associate Investigator(s): Allan L. Bucknell, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5
 Total number of subjects enrolled to date: 5
 Periodic review date: _____ Review results: _____

Objective(s): To document and assess the changes in the patellar tendon graft postoperatively, which include fibrous tissue formation, ligament vascularity, and other MRI characteristics.

Technical Approach: Patients included in this study will be at least 18 years of age, have undergone reconstruction of the ACL with an arthroscopically assisted patellar bone-tendon-bone technique.

Progress: After patients were enrolled on this study, we were informed that this study had gone on elsewhere and that results had been published. To continue would have been a waste of funds. Therefore, the study was terminated.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-54-91 Status: Terminated

Title: Prophylactic Intravenous Caffeine for the Prevention of Post Lumbar Puncture Headache Following Spinal Anesthesia.

Start date: 4 Jun 91	Estimated completion date:
Principal Investigator: Barbara L. O'Neill, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4
 Total number of subjects enrolled to date: 4
 Periodic review date: _____ Review results: _____

Objective(s): To determine if prophylactic intravenous caffeine is effective in decreasing the incidence of post lumbar puncture headache.

Technical Approach: Approximately 100 adult patients will be randomized into two groups. Group A will receive 0.5 gram caffeine sodium benzoate in 50 cc of 0.9% NaCl intravenous at the initiation of spinal anesthesia and upon arrival in the recovery room. Group B will receive 50 cc of 0.9% NaCl as outlined above. The incidence of post lumbar puncture headache will be evaluated by an unbiased observer on postoperative days 1, 3, and 5 either in person if the patient is hospitalized or by telephone if the patient has been discharged.

Progress: Study terminated. Principal investigator no longer at Brooke Army Medical Center.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-55-91 Status: Terminated

Title: Crystalloid Bolus-Facilitated Neuromuscular Blockade with Vecuronium or Atracurium.

Start date: 4 Jun 91	Estimated completion date:
Principal Investigator: Tara Chronister, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s): Douglas Loughhead, CPT, MC Kevin Olson, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To evaluate and compare intubating conditions with succinylcholine and bolus-facilitated vecuronium or atracurium.

Technical Approach: The study population will consist of 60 adults, male and female, ASA Class I or II with normal anatomy. Patients will be randomized to one of three groups. Group A will receive curare followed by a 60 second pause, then sodium thiopental and succinylcholine. Group B will receive vecuronium, a 10 ml bolus of saline, followed by sodium thiopental. Group C will receive atracurium, a 10 ml crystalloid bolus of saline then sodium thiopental. A stopwatch will be started for each group after administration of muscle relaxant and neuromuscular relaxation will be evaluated every 10 seconds by tetanic transcutaneous nerve stimulations.

Progress: Terminated secondary to technical approach difficulties.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-56-91 Status: Ongoing

Title: Urine Flow Rate Pre- and Post-Penile Prosthesis Implantation.

Start date: 4 Jun 91	Estimated completion date:
Principal Investigator: Kevin C. Shandera, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 8
 Total number of subjects enrolled to date: 8
 Periodic review date: Review results:

Objective(s): To determine 1) those patients with bladder outlet obstruction secondary to benign prostatic hypertrophy prior to penile prosthesis implantation and 2) the incidence and degree of decreased urine flow rate secondary to penile prosthesis induced urethral obstruction.

Technical Approach: All patients scheduled for penile prosthesis implantation will complete a questionnaire and undergo pre- and postoperative urine flow rate utilizing the Dantec Uroflowmeter¹.

Progress: No report provided by principal investigator.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-64-91 Status: Completed

Title: Outcomes Analysis of Radiotherapy and Radical Prostatectomy for Carcinoma of the Prostate.

Start date: 17 Jul 91	Estimated completion date:
Principal Investigator: Ian M. Thompson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To determine the chronologic increment in total health care outlays for the treatment of carcinoma of the prostate with either radiotherapy or radical prostatectomy.

Technical Approach: The CHAMPUS Claims Database (CCD) for the years 1989 and 1990 will be surveyed for all patients with a diagnosis of prostate cancer. The data on all such patients will be placed in a subfile on discs to allow processing of information on a personal computer. A decision analysis will be employed to select patients who have newly-diagnosed, localized carcinoma of the prostate and who undergo radiotherapy or radical prostatectomy for cure. Using this methodology, a subfile will be created of all patients who are treated for low-stage disease.

Progress: The database of almost 6,000 patients with adenocarcinoma of the prostate in the triservice CHAMPUS database has been identified. Over 4,000 hospitalizations were generated for this group of patients. A panel of three experts have been appointed (one urologist, one medical oncologist, and one radiotherapist) who have created a decision analysis which will interface with the database. With the database now completed, analysis is forthcoming.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-73-91 Status: Ongoing

Title: Does Magnesium Decrease the Incidence and Severity of Post-Cardiopulmonary Bypass Arrhythmias? A Double Blind, Randomized, Placebo Controlled Clinical Trial.

Start date: 30 Aug 91	Estimated completion date:
Principal Investigator: Paul D. Mongan, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s): Janet Hays, MAJ, MC Greg Bowman, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the correlation of mononuclear blood cell (MBC) Mg concentrations with myocardial Mg concentrations.

2) To determine the correlation of myocardial and MBC Mg concentrations with post-CPB arrhythmias (ventricular and supraventricular).

3) To determine if MgSO₄ administration (30 mg/kg followed by 15 mg/kg/hour x 4 hours) is efficacious in reducing the incidence of post-CPB arrhythmias.

4) To determine the correlation of right atrial and left ventricular myocardial Mg concentration.

Technical Approach: Patients will be randomized to receive either 30 mg/kg MgSO₄ or placebo (normal saline) during CPB followed by 15 mg/kg/hour or placebo for four hours. The right atrial appendage (200 mg) will be sampled for intracellular Mg concentration. A left ventricular myocardial sample (200 mg) will be obtained if the left ventricle is to be incised for valve repair or aneurysmectomy. Myocardial samples will be obtained prior to the administration of the study medication. The detection method for arrhythmias will be a continuous Holter monitoring (leads CM5 and II) both pre- and post-CPB.

Progress: We are awaiting laboratory support for the magnesium levels from Department of Clinical Investigation.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-74-91 Status: Completed

Title: Neoadjuvant Hormonal Therapy Prior to Radical Prostatectomy for Clinical Stage A and B Carcinoma of the Prostate.

Start date: 30 Aug 91	Estimated completion date:
Principal Investigator: Ian M. Thompson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Eric J. Zeidman, LTC, MC Edward J. Mueller, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): 1) To determine if neoadjuvant hormonal therapy prior to radical prostatectomy results in an improvement in pathologic stage of carcinoma of the prostate.

2) To determine whether complication rates are reduced following radical prostatectomy which is preceded by neoadjuvant hormonal therapy.

Technical Approach: Sixty patients with clinically stage A1, B1, B1 (t1-2) carcinomas of the prostate will be randomized to receive either radical prostatectomy or neoadjuvant hormonal therapy. Patients eligible for the study must have a negative staging evaluation including normal bone scan and no evidence of extraprostatic disease. All patients will have preoperative PSA and acid phosphatase drawn and assigned a Gleason's histologic grade.

Progress: This study has been closed. It has been superceded by a multi-institution study of the same design.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-75-91 Status: Ongoing

Title: Influence of Injectate Temperature on Spinal Anesthesia with Isobaric Lidocaine.

Start date: 30 Aug 91	Estimated completion date:
Principal Investigator: Douglas J. Loughhead, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s): Kevin Kenworthy, CPT, MC Cheryl Wesen, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To evaluate the effect of injectate temperature (37°C vs 20°C) during isobaric lidocaine spinal anesthesia with respect to 1) onset of blockade, 2) maximum sensory level of blockade attained, 3) quality of analgesia, and 4) duration of blockade.

Technical Approach: This is a randomized, double blind, prospective study. Adult male patients scheduled for inguinal herniorrhaphy are eligible to participate. They will be randomized to receive spinal anesthesia with isobaric lidocaine equilibrated to 20°C or isobaric lidocaine equilibrated to 37°C.

Progress: No report provided by principal investigator.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-76-91 Status: Ongoing

Title: Efficacy of Steroid in Reducing Post-Tonsillectomy Morbidity.

Start date: 30 Aug 91	Estimated completion date:
Principal Investigator: Todd M. Rumans, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Otolaryngology	Associate Investigator(s): Sylvester G. Ramirez, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 18
Total number of subjects enrolled to date: 19

Periodic review date: Review results:

Objective(s): To determine whether the use of intravenous perioperative steroids (dexamethasone) enhances the overall recovery in patients undergoing tonsillectomy: (1) by reducing postoperative pain, 2) by reducing postoperative swelling, and/or 3) allowing improved oral intake.

Technical Approach: The study group will include approximately 50 study subject and 50 controls. This study will compare post-tonsillectomy 1) pain, 2) tolerance of diet, i.e., liquids vs soft vs regular, 3) swelling, 4) temperature 5) weight fluctuation and 6) complications between patients receiving dexamethasone or placebo perioperatively.

Progress: Thus far, 19 patients have enrolled out of an anticipated 100 needed. We have had several patients refuse this study, and have also had patients that did not have study offered erroneously. Will forward information to patients prior to surgery in effort to increase our rate of participation.

Due to technical difficulties, we were unable to begin signing people to study until early 1992.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-89-91 Status: Ongoing

Title: Open Label Trial of Centoxin (HA-IA) Treatment of Presumed Gram-Negative Sepsis

Start date: 7 October 1991	Estimated completion date:
Principal Investigator: Richard B. Hecker, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/SICU	Associate Investigator(s): J. William Kelly, MAJ, MC David P. Ciceri, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 15
 Total number of subjects enrolled to date: 17
 Periodic review date: _____ Review results: _____

Objective(s): To provide a means by which a critically ill patient with presumed gram-negative sepsis may receive investigational HA-1A treatment.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: FINAL REPORT. A total of 17 doses of 100 mg HA-IA were administered IAW established protocol to 11 subjects. Four patients received multiple doses (two patients received 2 doses; two patients received 3 doses). Of the 11 patients, 6 died and the other 5 were discharged from the surgical ICU.

SUMMARY:

Single dose: N=7 Alive = 3 Dead = 4

Double dose: N=2 Alive = 0 Dead = 2

Triple dose: N=2 Alive = 2 Dead = 0

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-90-91 Status: Ongoing

Title: Phase I Protocol for the Evaluation of Active Immunization Against LHRH in Patients with Metastatic Cancer of the Prostate.

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: Ian M. Thompson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s): Peter Randin, MC Edward J. Mueller, LTC, MC Eric J. Zeidman, LTC, MC Paul Desmond, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4

Total number of subjects enrolled to date: 4

Periodic review date: Review results:

Objective(s): 1) To determine whether active immunization with a luteinizing hormone releasing hormone (LHRH) based vaccine will result in a significant immune response to LHRH in patients with metastatic prostatic cancer.

2) To determine if immunization against LHRH will cause suppression of luteinizing hormone (LH) and follicle stimulating hormone (FSH) levels in these patients.

3) To observe patients for signs of adverse effects following immunization.

Technical Approach: Four patients from BAMC will be referred on the study. The LHRH vaccine will be administered by Dr. Ravdin at the University of Texas Health Science Center on three occasions at two week intervals. Patients will return to BAMC for follow-up at monthly intervals for the first six months and then every three months for up to two years.

Progress: Four patients have enrolled in this study and are currently being followed. One patient experienced a significant increase in LHRH antibodies after the first cycle of immunizations. A second series of immunizations was approved and accomplished. With these, two additional patients achieved measurable anti-LHRH antibodies. Fascinatingly, patients who achieved this response also had a decrease in PSA although they are castrated! A larger Phase I/II trial is now planned.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-92-91 Status: Ongoing

Title: Does Preoperative Axillary Ultrasound and Tumor DNA Content Predict Axillary Lymph Node Metastases in Breast Cancer Patients with Clinically Negative Axilla.

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: Frank M. Robertson, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/SICU	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To prospectively analyze a group of variables to include size of primary tumor, receptor status, presence of adenopathy on axillary ultrasound, ploidy status and percent s-phase in breast cancer patients with clinically negative axilla.

Technical Approach: Data to include age, primary tumor size, estrogen receptor status, progesterone receptor status, axillary ultrasound, ploidy status, s-phase fraction, and final anatomic pathology results will be collected on all patients treated for breast cancer at BAMC for a period of 18 to 24 months. In patients with suggestive physical exams or mammograms, the ultrasound will be obtained prior to any surgical intervention such as biopsy.

Progress: Due to a manpower shortage, this protocol is in a hold status. A lack of ultrasound technical support has been the problem. I don't think this will change in the near future.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-93-91 Status: Ongoing

Title: Aeric and Particulate Microemboli as Etiologic Factors in the Development of Neurobehavioral Dysfunction Following Cardiopulmonary Bypass and Vascular Surgery: An Outcome Study.

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: Charles P. Kingsley, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/ Anesthesiology	Associate Investigator(s): Maurice Albin, ND
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To determine the incidence of air and particulate emboli during cardiopulmonary bypass (CPB) using transcranial doppler ultrasound as a detection device and to detect, correlate, and follow postoperative neurologic and psychometric changes seen in patients.

Technical Approach: This is a multicenter outcome study with UTHSCSA and Wilford Hall Medical Center. 125 patients requiring CPB will be enrolled with 25 patients for peripheral vascular procedures not requiring CPB serving as controls. Psychologic testing and neurologic evaluation will be performed preoperatively, at discharge and at 6 weeks, 6 months and 1 year after discharge. Intraoperative noninvasive testing will consist of transcranial doppler ultrasound (TCD) for the detection of air and particulate emboli and EEG monitoring by a commercially available processed EEG monitor. Anesthetic regimens will be standardized.

Progress: Study has been reviewed by Heart Blood and Lung group of the NIH. Awaiting funding.

Detail Summary Sheet

Date: 4 Feb 93 **Protocol Number:** C-92-1 **Status:** Terminated
Title: Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Trial

Start date:	Estimated completion date:
Principal Investigator: LTC Ian M. Thompson, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ **Review results:** _____

Objective(s): To determine if the application of several screening tests for prostate, lung, colorectal, and ovarian cancers can reduce mortality from these diseases. Additionally, we will assess several parameters associated with each screening modality including sensitivity, specificity and positive predictive value.

Technical Approach: Patient contact will be through a personalized letter targeted to the entire retired military population announcing the PLCO study criteria and benefits and inviting their active participation in the cancer early detection progress.

Progress: BAMC competed against other centers. Our cost was too high. For this reason, study will not be performed.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-19

Status: Terminated

Title: Arthroscopic Repair of Glenoid Labral Tears in Traumatic Anterior Shoulder Dislocations in Young Adults

Start date:	Estimated completion date:
Principal Investigator: MAJ Brian D. Allgood, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Orthopaedics	Associate Investigator(s): CPT Joshua M. Zimmerman, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To determine the effect of arthroscopic glenoid labral tear repair in traumatic anterior shoulder dislocators in the age group 17-22 on range of motion, time to return to full function, and redislocation rate.

Technical Approach: All male and female patients aged 17-22 with radiographic or historical evidence of first-time anterior shoulder dislocation within two weeks of referral to the BAMC Orthopaedic Surgery Service are eligible for inclusion in this study. All patients will undergo MRI to evaluate the glenoid labrum.

Progress: Protocol deleted. Insufficient patients entering study.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-22 Status: Terminated

Title: Retrospective Analysis of Thymomas' Surgical and Histologic Staging as a Predictor for 10-Year Mortality

Start date:	Estimated completion date:
Principal Investigator: CPT James M. Williams, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/General Surgery	Associate Investigator(s): LTC Greg Bowman, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): 1) Examine relationship of surgical and histologic staging as predictor for 10 year survival. 2) Examine relationship of age at diagnosis with 10-year survival. 3) Examine relationship of autoimmune diseases and secondary cancers in patients with thymomas.

Technical Approach: Compare the outcomes in the current study with the outcomes of larger studies involving patients with thymomas.

Progress: Study terminated due to PCS of principal investigator to Ft. Hood, Texas.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-26

Status: Ongoing

Title: Determination of Vecuronium Bromide Requirements in Nonthermally Injured Patients

Start date:	Estimated completion date:
Principal Investigator: CPT Roger Wesley, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology	Associate Investigator(s): CPT Paul D. Mongan, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the ED₉₅ of vecuronium bromide for train-of-four twitch height depression in the nonthermally injured patient. 2) To compare the ED₉₅ determined for these patients to that determined for thermally injured patients.

Technical Approach: Patients will be premedicated at the discretion of the anesthesiologist. After placement of monitors and preoxygenation, patients will be induced with sufentanil citrate and thiopental sodium or ketamine as indicated by the patient's condition.

Progress: No progress report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-27 Status: Ongoing

Title: Analysis of Foot Surface Stress in Parachute Landing Falls

Start date:	Estimated completion date:
Principal Investigator: CPT James P. Stannard, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Orthopaedics	Associate Investigator(s): CPT Robert Harris, MC
Key Words: PLF's Foot Surface Stress	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0
 Total number of subjects enrolled to date: 0
 Periodic review date: Review results:

Objective(s): To analyze foot surface stress in PLF-s under varying conditions (footgear, terrain, velocity) utilizing an in-shoe foot force analysis system. This data will be used to: 1) understand the mechanics of high impact landing; 2) design and test equipment to protect paratroopers during airborne missions; and 3) recommend changes in training regimens and landing techniques.

Technical Approach: All jumps will be performed from a platform or a horizontal "slide" by U.S. Army paratroopers on active jump status. An F-scan force analysis system will be used to measure landing forces during all jumps. System consists of an in-shoe transducer that is made up of 960 element matrix of 5mm square sensors linked to a 386 computer.

Progress: Delay in providing airborne soldiers at Ft Bragg, NC. Currently scheduled for jump during week of 12-19 April 93 at Ft Bragg, NC.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-28

Status: Completed

Title: Effects of Isoflurane on the Amplitude and Latency Characteristics of Transcranial Magnetic and Spinal Motor Evoked Potential Monitoring

Start date:	Estimated completion date:
Principal Investigator: CPT Paul D. Mongan, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): 1) To determine the variability of amplitude and latency characteristics of motor evoked potentials generated by transcranial magnetic and spinal electric stimulation and recorded from the spinal cord, the sciatic nerve and the compound motor action potential of the gastrocnemius.

Technical Approach: a. Study design - prospective patient controlled evaluation of the effect of isoflurane on the MEP response generated by TcM and spinal cord electric stimulation with recording of the scMEP, peripheral NAP. b. Population -Inclusion criteria - 10 ASA 1 or 2 orthopaedic patients scheduled for elective back surgery.

Progress: Study completed. Results in initial stages. Will be published at a later date.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-35 Status: Ongoing

Title: Use of a Foot Compression Pump in the Prevention of Deep Vein Thrombosis in Hip Fractures

Start date:	Estimated completion date:
Principal Investigator: CPT James P. Stannard, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Orthopaedics	Associate Investigator(s): CPT Robert Harris, MC CPT Brian Allgood, MC COL Allan Bucknell, MC
Key Words: DVT, Foot Pump Total Joint Arthroplasty	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 29
 Total number of subjects enrolled to date: 40
 Periodic review date: Review results:

Objective(s): To determine the clinical usefulness of the AVI foot pump as prophylaxis for deep venous thrombosis associated with hip fractures in individuals greater than 40.

Technical Approach: All male and female patients greater than 40 years of age sustaining a femoral neck fracture of intertrochanteric fracture presenting to the BAMC Orthopaedic Surgery Service within 48 hours of injury and requiring operative intervention without a history of prior deep venous thrombosis, without concomitant lower extremity precluding the use of a foot pump, not on warfare in therapy for other medical problems, and not pregnant will be eligible for inclusion in the study.

Progress: Total patients - 40 hip fractures. 0 DVT in foot pump group. 4 DVT in foot pump group. Statistical analysis demonstrates statistical significance in femoral neck hip fractures. Not significant in intertroch. 60-80 hips needed before statistical signs achieved.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-42 Status: Ongoing

Title: Superoxide Dismutase (r-hSOD) in the Management of Acute Head Injury

Start date:	Estimated completion date:
Principal Investigator: Steven L. Klein, LCDR	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Neurosurgery	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To evaluate the efficacy of r-hSOD in the management of severe acute head injury. To evaluate the metabolic, biochemical, and vascular drug related responses to head injury in humans.

Technical Approach: As indicated in the protocol.

Progress: This study was held up for greater than one year by FDA. Currently there is an attempt to restart this project. However, I am not sure that our numbers will allow this currently.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-45 Status: Ongoing

Title: The Incidence of Sexual Dysfunction After Transurethral Prostate Surgery Using Rigiscan Penile Tumescence and Rigidity Device

Start date:	Estimated completion date:
Principal Investigator: Duane Cespedes, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Ian M. Thompson, LTC, MC Eric J. Zeidman, MAJ, MC Samuel Peretsman, MD Alvin L. Sago, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To determine the qualitative and quantitative effect of transurethral surgery upon erectile potency as measured by both sexual function instruments (inventory/questionnaire) and by Rigiscan tumescence/rigidity monitoring.

Technical Approach: All patients will be asked to complete a standardized sexual function questionnaire. Rigiscan monitoring will be performed on all patients within two months prior to prostate surgery and again three months following surgery. If at the three-month interval, the patient is experiencing any medical or physical problem which might interfere with the Rigiscan interpretation, the Rigiscan testing will be postponed for a clinically-appropriate period.

Progress: No progress report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-47

Status: Ongoing

Title: Acute Normovolemic Hemodilution: Comparison of the Use of Mixed Venous Oxygen Saturation to a Standard Technique

Start date:	Estimated completion date:
Principal Investigator: CPT Paul D. Mongan, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$33,386.00

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): 1) To evaluate a standard technique of hemodilution with regard to cardiovascular changes and compare this information to the safe limits of hemodilution which we will establish. 2) To establish the limits of safety of this technique based on recognized physiologic parameters by using mixed venous oxygen saturation as a guide to limit the amount of blood removed and to guide the need for transfusion therapy.

Technical Approach: Written informed consent will be obtained from the parents of 20 healthy patients scheduled for major spine surgery. A routine preoperative assessment will be performed by the anesthesia team and preoperative laboratory tests will be obtained. All patients will have anesthesia induced via mask with oxygen, nitrous oxide and halothane or with the intravenous agent thiopental. Intubation will be facilitated by the use of vecuronium bromide at a dose of 0.1 mg/kg.

Progress: Low rate of enrollment is secondary to decrease in scoliosis operation at BAMC and inability of Dr. Fontana to get free time to staff cases at Children's Hospital in DC.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-48

Status: Ongoing

Title: Nitrate Metabolism in Critically Ill Patients.

Start date:	Estimated completion date:
Principal Investigator: Frank M. Robertson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Critical Care	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To measure urinary nitrate and urea levels in critically ill patients using the stable isotope-N15-arginine, and compare these with normal controls.

Technical Approach: A group of 4-8 critically ill patients with sepsis and/or multiple organ failure will be compared to a similar group of stable general surgery patients.

Progress: No annual reported provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-55 Status: Completed

Title: Collagraft Study Addendum--Blood Chemistries and Immunological Testing

Start date:	Estimated completion date:
Principal Investigator: COL Allan L. Bucknell, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Orthopaedics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost: 0.00	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 3

Periodic review date: _____ Review results: Published

Objective(s): Final safety testing of COLLAGRAFT for PMA.

Technical Approach: Evaluation of PMA patients for CPK, rheumatoid factor and antinuclear antibodies at yearly intervals up to three years postoperatively. If an abnormal CPK is noted, tests for Adolase, SGOT, SGPT, and antiovine collagen antibodies will be run.

Progress: Study completed. This was a multicenter project and BAMC had a very small contribution. Collagraft has received FDA approval based upon this study.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-57

Status: Ongoing

Title: Prostatic Intraepithelial Neoplasia as a Predictor of Subsequent Development of Carcinoma of the Prostate.

Start date:	Estimated completion date:
Principal Investigator: Ian M. Thompson, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): COL Moo Cho, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To determine the association of PIN and AAH with subsequent development of CAP in men with benign prostatic hyperplasia (BPH).

Technical Approach: The slides of the pathologic evaluation of the benign glands in the 333 men who underwent TURP for BPH between 1980 and 1983 will be recovered. The slides will then be forwarded to Dr. Michael Brawer at the University of Washington for evaluation. The evaluation will be made in a 'blinded' manner - i.e., Dr. Brawer will not be aware of which patients subsequently developed carcinoma of the prostate.

Progress: This study has yet to be activated. Awaiting support from the VA Cooperative Trials group for pathologic processing.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-60 Status: Ongoing

Title: A comparison of intraoperative patient controlled sedation with sedation provided by an anesthesiologist for surgery performed under regional anesthesia.

Start date: Mar 92	Estimated completion date: Jun 93
Principal Investigator: John C. Talbot, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s): Joseph P. Ducey, LTC, MC
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period: 38
 Total number of subjects enrolled to date: 38
 Periodic review date: Review results:

Objective(s): To compare intraoperative patient controlled sedation administered on demand by a PCA infuser, with sedation provided by an anesthesiologist during regional anesthesia. The study will evaluate the feasibility of patient controlled sedation, patient and physician acceptance of this method, as well as patient benefits and adverse effects.

Technical Approach: Forty (40) ASA I and II adult patients (ages 18-70) scheduled for elective surgery under spinal or regional anesthesia will be investigated. Patients will be randomized into two groups. No pre-op sedations, hypnotics or opioids will be given. Routine monitors will be applied (continuous ECG, pulse oximetry, automated oscillometric blood pressure, nasal CO₂ and precordial stethoscope), and patients will be placed on 3 liters per minute oxygen by nasal prongs. Patients in groups one and two will receive a bolus of 0.5mg/kg of propofol over 2 minutes before performing the regional anesthetic.

Progress: Further sedation in group one will be provided by anesthesiologists using propofol as deemed necessary, while additional sedation in group two is administered on demand by a PCA infuser.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-66

Status: Ongoing

Title: Impact of Dietary Manipulation on Prostate Cancer

Start date:	Estimated completion date:
Principal Investigator: Ian M. Thompson, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Barbi Helfrick, RN Susan Wise Wilson, MS, RD, LD Forrest Newman, LTC, MC Jean M. Johnson, Ph.D., RN
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): 1) To determine if a low fat, high fiber diet reduces serum prostatic specific antigen (PSA) in patients with carcinoma of the prostate. 2) To assess the impact of a low fat, high fiber diet on a patient's quality of life. 3) To assess the relationship between health beliefs, self-efficacy, social support and compliance with a low fat, high fiber diet.

Technical Approach: Pilot study will describe the impact of dietary manipulation on serum PSA, the factors which may contribute to dietary compliance, and the overall effect on quality of life. Subjects will be their own controls. The study group will consist of thirty men with known carcinoma of the prostate identified through the Urology Service Tumor Registry and who have (1) stable disease, (2) intact hormonal axis, and (3) elevated PSA (greater than 4 ng/ml as measured by the Hybritech assay). All men will be informed as to the nature of the study and will sign informed consent.

Progress: Study continues for data collection.

Detail Summary Sheet

Date: 4 Feb 93 **Protocol Number:** C-92-67 **Status:**

Title: Pilot Study of Intravesical Bacillus Calmette-Guerin (BCG) therapy for refractory interstitial cystitis.

Start date:	Estimated completion date:
Principal Investigator: Eric J. Zeidman, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Ian M. Thompson, LTC, MC Edward J. Mueller, LTC, MC Paul N. Desmond, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6

Total number of subjects enrolled to date: 6

Periodic review date: **Review results:**

Objective(s): To determine if intravesical Bacillus Calmette-Guerin therapy results in an improvement in interstitial cystitis pathologic signs and symptoms.

Technical Approach: Twenty patients with refractory interstitial cystitis will be given six weekly intravesical treatments with one vial of Bacillus Calmette Guerin (tice), BCG vaccine. Each 50mg vial will be reconstituted with 1.0 ml of steril injectable preservative-free saline. This will then be diluted with 50 cc of preservative-free saline for intravesical administration by gravity.

Progress: A total of 6 patients have been entered and hormonal studies as well as tumor markers analyzed. Thus far, PSA determinations have changed very little in these patients. No distinct trend can be noted.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-74 Status: Ongoing

Title: A Preliminary Study on Multiple Linear Regression Analysis of Apnea Indices as a Function of Cephalometric Measurements in Preoperative and Postoperative Patients

Start date:	Estimated completion date:
Principal Investigator: CPT John H. Romanow, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Otolaryngology	Associate Investigator(s): MAJ Sylvester Ramirez, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): A preoperative cephalogram and polysomnogram will be obtained in adult patients and compared to published norms.

Technical Approach: As part of their evaluation at the sleep clinic at BAMC, patients undergo a workup consisting of a history and physical, spirometry, TFTs, ABGs, cephalometric analysis and polysomnography. This is a preliminary study and thirty patients will be chosen who have OSA by polysomnography and choose surgical therapy.

Progress: No annual report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-84

Status:

Title: Treatment of Stage C Carcinoma of the prostate with Adjuvant Hormonal Therapy Followed by Radical Prostatectomy.

Start date:	Estimated completion date:
Principal Investigator: LTC Ian M. Thompson, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): 1) To evaluate the potential benefit of neoadjuvant hormonal therapy on the disease free survival rates in Stage C (T3NOMO) carcinoma of the prostate. 2) To assess the qualitative and quantitative toxicities of patients with Stage C prostate carcinoma with androgen blockade followed by surgery. 3) To assess the effect of neoadjuvant hormonal therapy on prostate intra-epithelial neoplasia (PIN).

Technical Approach: All eligible patients will receive neoadjuvant hormonal therapy prior to radical prostatectomy. Twenty eligible patients will be recruited.

Progress: Study ongoing and data accrual continues.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-90 Status: Terminated

Title: A Double-Blind, Randomized, Placebo-controlled, Multicenter Study to Determine the Efficacy of MK-434 in Patients with Benign Prostatic Hyperplasia Prior to Prostatectomy.

Start date:	Estimated completion date:
Principal Investigator: LTC Ian M. Thompson, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s): Edward J. Mueller, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4
 Total number of subjects enrolled to date: 4
 Periodic review date: _____ Review results: _____

Objective(s): a) To evaluate the biochemical efficacy on MK-434 by measurement of plasma and intraprostatic concentrations of T and DHT in the prostate after 28 days of treatment in men with BPH awaiting surgical therapy. b) To determine the biologic effect and correlate inhibition of intraprostatic androgens to oral doses of MK-434. c) To obtain further data on the safety, tolerability, and pharmacodynamics of MK-434.

Technical Approach: This is a double-blind, randomized placebo-controlled, study in which approximately 80 patients with benign prostatitis hyperplasia will receive MK-434 5 or 25 mg, finasteride 5 mg, or placebo for 28 days prior to surgery.

Progress: This study was terminated by the sponsor on 3 December 1992 due to the development of liver tumors in some of the laboratory animals. One patient was taking the study medication and it was stopped immediately. The data on all patients was picked up and the study was closed.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-91

Status: Ongoing

Title: Hormonal Influences on Cultural Osteoblasts from Mature and Senile Rats

Start date:	Estimated completion date:
Principal Investigator: MAJ Jay D. Mabrey, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Orthopaedic Surgery	Associate Investigator(s): Mona M. Everett, Ph.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To study the effects of aging on osteoblasts. We will compare osteoblasts cultured from mature rats (8 months of age) to those of a population of senile rats (24 months of age). Parameters examined will be osteoblast plating efficiency, cell growth, alkaline phosphatase activity and distribution, alkaline phosphatase characteristics, and response of cultured osteoblasts to hormones.

Technical Approach: Bone fragments from the long bones of mature and old Fischer 344 rats will be cultured in 25 cm² flasks. In addition to the appropriate vehicle controls, one of several agents will be added. Growth parameters, nodule formation, and bone-related markers will be measured.

Progress: We are now using a different osteoblast extraction protocol similar to the method described by Robey and Termine. Fragments of cortical bone are incubated with collagenase and the fragments are then incubated in alpha MEM. At this point, the new technique has resulted in much slower growth of the cells, but the potential to gather more information from the cultures should make it worthwhile. Additionally, we plan to characterize the cultures with respect to osteocalcin production in order to prove that they are indeed osteoblasts. The latest harvest of cells comes from a cohort of Fischer 344 rats being raised in a pathogen free environment by Dr. Nelson's lab at the University. The rats are all aging at the same rate, meaning that we will not have access to the 24 month old rats until 18 months from now.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-92 Status: Completed

Title: Prospective Comparison of Balloon Dilatation

Start date:	Estimated completion date:
Principal Investigator: LTC Ian M. Thompson, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 27
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Progress: This study enrolled patients with benign prostate hyperplasia in a single arm, non-blinded evaluation of the efficacy of the Surgitek prostate balloon dilatation catheter. A total of 27 patients were enrolled at BAMC. The unique attribute of this site was the preoperative and postoperative MRI scans of the prostate.

Patients were evaluated with uroflowmetry, measurement of postvoid residual urine, as well as with a BPH symptom score. Most patients had improvement in one parameter or another although the correlation of these parameters was inconsistent. As an example, some patients noted improvement in their symptom scores but worsening of objective parameters of measurement. In others, the reverse was the case.

All patients have been followed for at least eighteen months. Only one complication was noted. In this patient, during retrieval of the balloon from the prostatic fossa, a laceration of the urethra was noted. This was treated with foley catheterization and no sequelae have been noted. MRI examinations of the prostate revealed that an anterior commissurotomy did not generally occur. Real-time ultrasonography during prostate dilatation revealed that, despite endoscopic monitoring of the balloon, retrograde migration was almost universally the case, making complete dilatation almost impossible.

At this point, the study has been closed at Brooke Army Medical Center. Patients will continue to be followed on an annual basis and treated according to standard clinical practice.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-48-90 Status: Ongoing

Title: Evaluation of a Novel Aminoglycoside Dosing Nomogram.

Start date: 27 Mar 90	Estimated completion date:
Principal Investigator: Thomas C. Shank, CPT, MS	Facility: Brooke Army Medical Center, Texas
Department/Service: Pharmacy Service	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1
 Total number of subjects enrolled to date: 7
 Periodic review date: n/a Review results: _____

Objective(s): To evaluate the predictive accuracy of a novel aminoglycoside dosing nomogram.

Technical Approach: Adult male and female patients who have an infection requiring gentamicin will be admitted to the study. When the patients' serum gentamicin level has reached steady state, one of the study participants will administer one dose of gentamicin via a syringe pump and draw both nadir (trough) and peak serum gentamicin samples. Each sample will be divided into two parts, one will be sent to the DPALS laboratory for routine analysis and the other will be analyzed in DCI by one of the study participants.

Progress: Seven patients have been enrolled in this study. No adverse effects have been noted.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-42-88 Status: Terminated

Title: Evaluation of Routine Human Immunodeficiency Virus (HIV) Screening Program in Hospitalized Patients.

Start date: 29 Mar 88	Estimated completion date:
Principal Investigator: Janice N. Longfield, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Preventive Medicine Service	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 1205 (FY 90)

Periodic review date: Review results:

Objective(s): To assess the impact of implementing a routine HIV screening in hospital admissions in a tertiary care hospital in an area of low prevalence for the HIV infection.

Technical Approach: Evaluate implementation of routine screening of hospital admissions on selected medicine and surgery wards via a questionnaire requiring data from chart review. Subsequent correlation with laboratory test results and laboratory statistics. Outcome variables include acceptance rate for screening by nonactive duty patients, rate of positive test results, hospital day when results become available, etc. Outcome variables will be categorized by ward, service, and demographic characteristics.

Progress: Study is terminated. Staff duties and other research projects had a higher priority. The Centers for Disease Control recently published a study of this issue after collecting data from 20 U.S. hospitals.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-9 Status: Terminated

Title: A Study to Evaluate the Effects of Heparinized and Nonheparinized Flush Solution on the Patency of Pressure Monitoring Lines

Start date:	Estimated completion date:
Principal Investigator: CPT Vinnette Bullock, AN	Facility: Brooke Army Medical Center, Texas
Department/Service: Nursing/Med-Surg Section USAMEDD Ctr	Associate Investigator(s): LTC Carol Reineck, AN
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To participate as one site in the Thunder Project which is a large-sample, multi-site research project sponsored by the American Association of Critical Care Nurses.

Technical Approach: Evaluate the effect of heparinized and nonheparinized flush solutions on the patency of arterial pressure monitoring lines.

Progress: Terminated in November 1992. BAMC had 30 subjects.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-77-91 Status: Terminated

Title: Effect of a Six-Week Training Program on Middle Trapezius Strength and Resting Scapular Position in Standing Subjects.

Start date: 30 Aug 91	Estimated completion date:
Principal Investigator: Randy A. Green, 2LT, SP	Facility: Academy of Health Sciences
Department/Service: Physical Therapy Section	Associate Investigator(s): Cynthia L. Weppler, 2LT, SP Roger L. Behrman, 2LT, SP Scott W. McDonough, 2LT, SP
Key Words: Strength Training Scapula Middle Trapezius	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 44
Total number of subjects enrolled to date: 44
Periodic review date: 4 Dec 92 Review results:

Objective(s): To investigate the effect of a six week training program on the resting scapular position of standing subjects and on middle trapezius muscle strength.

Technical Approach: This study will train and test 60 healthy male active duty military personnel, ages 18-30. The investigators will perform pre-test measurements (scapular position/strength, and trunk flexion/extension) and randomly assign the subjects into test and control groups. Test group subjects will perform scapular strengthening exercises and control group subjects will perform William Flexion Exercises. Each group will perform their respective exercises three times per week for six weeks during September-October 1991. Each session will last approximately 15 minutes and take place prior to regular physical training. Upon completion of the six week training program, the investigators will record post-training measurements on subjects of both groups.

Progress: Our study demonstrated no effort of a five-week strengthening program for the middle trapezius muscle on scapular position. We have elected to terminate the study due to several factors: The study was shortened to five weeks because of subject committments. The intensity of our exercise program could have been greater, and finally, our subject size, forty-four, fell short of our goal of sixty.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-78-91 Status: Completed

Title: Comparison of Time to Peak Torque Values for the Peroneal Muscles Between Patients with Recurrent Lateral Ankle Sprains and Normal Subjects.

Start date: 30 Nov 91	Estimated completion date:
Principal Investigator: Patty Krupka, 2LT, SP	Facility: Academy of Health Sciences
Department/Service: Physical Therapy Section	Associate Investigator(s): Rebecca Geeseman, 2LT, SP Heather Khan, 2LT, SP Lynne Morris, 2LT, SP
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: 60	
Total number of subjects enrolled to date: 60	
Periodic review date: Review results:	

Objective(s): To determine if there is a difference between evetor time to peak torque values of individuals who have never sprained their ankles and individuals who have sprained the same ankle two or more times.

Technical Approach: This study will involve 60 individuals of both genders between the ages of 18 and 45. The right leg will be the tested leg for the control group and the leg with the chronically sprained ankle will be the tested leg for the affected group. All subjects will be isokinetically tested on the Biodex for evetor time to peak torque values. Subjects will do four to six submaximal trial repetitions and then, two maximal repetitions for practice. Following a two minute rest period, subjects will perform three maximal repetitions. The time to peak torque value will be the average of these three repetitions.

Progress: Final report. The data did not show a significant difference between the control and test group with either concentric ($t=1.23$, $p>0.10$ or eccentric ($t=0.12$, $p>0.10$) muscle action. This was consistent with Nawoczinski's findings that looked at the reaction time of the peroneal muscles to a sudden inversion stress. A more controlled subject population and a change in the testing procedure may help to produce more significant results, or at least clarify the lack of relationship between recurrent ankle sprains and time to peak torque values. It appears questionable whether time to peak values need to be addressed in an ankle rehabilitation program.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-79-91 Status: Ongoing

Title: The Effects of Therapeutic Application of Heat or Cold Followed by Static Strength on Hamstring Muscle Strength.

Start date: 30 Aug 91	Estimated completion date:
Principal Investigator: Teresa Brashear, 2LT, SP	Facility: Academy of Health Sciences
Department/Service: Physical Therapy Section	Associate Investigator(s): Brent F. Taylor, 2LT, SP Christopher A. Waring, 2LT, SP
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To determine whether therapeutic application of superficial heat or superficial cold prior to static stretch will increase the efficacy of the stretch in increasing hamstring muscle length in a population of healthy active duty military subjects and if a difference exists, determine which treatment is more effective.

Technical Approach: This study will examine 12 male and 12 female active duty military subjects, age 20-35. Each subject will be treated on three separate occasions. During each session, the subjects will receive one of three treatments: heat application followed immediately by static stretch, cold application followed immediately by static stretch, or static stretch alone which will serve as the control.

Progress: No report provided by principal investigator.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-80-91 Status: Completed

Title: Eccentric and Abdominal Curl Training Effects on Conventional Sit-up Performance.

Start date: 30 Aug 91	Estimated completion date:
Principal Investigator: Patricia A. Sargeant, CPT, SP, USAF	Facility: Academy of Health Sciences, Texas
Department/Service: Physical Therapy Section	Associate Investigator(s): Joseph M. Malloy, CPT, SP David E. Meyer, 1LT, SP Gregory A. Weaver, 2LT, SP
Key Words: Sit-up Abdominal Training	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 282
 Total number of subjects enrolled to date: 0
 Periodic review date: _____ Review results: Over time, the number of sit-ups performed increased regardless of groups (P<.0001) but no significant difference existed among groups. (p=.98)

Objective(s): To determine which of three different training methods (concentric, eccentric, or abdominal curl) will have a significant effect on conventional sit-up performance.

Technical Approach: Subjects acted as their own controls. After completing an Army Physical Fitness Test (APFT), subjects participated in six weeks of unit physical training. They were rank ordered by their pre-test score, assigned randomly by matched groups to one of three training groups-eccentric, concentric, or abdominal curl; abdominal training was conducted in addition to unit training. All groups performed at least two minutes of concentric sit-ups during abdominal training plus the prescribed training protocol. Subjects were administered another APFT after six weeks of training. Means and standard deviations of pre- and post-test raw sit-up scores were computed. A two-factor analysis of variance with repeated measures on one factor was used to determine significance among the groups and between trials ($\alpha=.05$). Over time, the number of sit-ups performed increased regardless of group assignment ($p < 0.0001$) by an average of 11 sit-ups but no significance difference existed among groups ($p=.98$).

Progress: This study provides evidence that any of the three training routines, when preceded by two minutes of concentric sit-ups will significantly C-80-91 (continued)

increase the number of sit-ups performed on an APFT. Therefore, Commanders can use a variety of abdominal exercises to improve sit-up scores.

Detail Summary Sheet

Date: 3 Feb 93 Protocol Number: C-81-91 Status: Ongoing

Title: Relationship Between Isokinetic and Functional Test of the Quadriceps.

Start date: 30 Aug 91	Estimated completion date:
Principal Investigator: Scott Shaffer, 2LT, SP	Facility: Academy of Health Sciences, Texas
Department/Service: Physical Therapy Section	Associate Investigator(s): Eric Payne, 1LT, SP Lewis Gabbard, 1LT, SP Matthew Garber, 2LT, SP
Key Words: Neuromuscular adaptation Functional testing	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 57

Total number of subjects enrolled to date: 57

Periodic review date: Review results:

Objective(s): 1) To determine if eccentric and concentric isokinetic tests of the right quadriceps muscle of a healthy active duty military male population have a significant correlation with functional tests.

2) To determine if there is a statistically significant learning effect which occurs with the functional test.

Technical Approach: This descriptive study is to determine whether a correlation exists between peak torque values and values from three isotonic functional tests: 1) one legged hop for distance, 2) cross-over hop for distance, and 3) one legged triple jump for distance. One hundred health male active duty military personnel between 18 and 45 years will be tested on the Kin/Com isokinetic dynamometer at speeds of 60 and 180 degrees per second. Isotonic functional tests will be measured during the same isokinetic testing session.

Progress: The three subjects who did not perform session #2 testing were a result of: 1) One subject had prior military obligation on day 2 testing. 2) One subject's day #1 testing results were lost, secondary to a computer error. 3) One subject was not able to perform an eccentric contraction at 180 degrees on day #2 testing secondary to pain. This pain resolved in 24 hours and this subject was fully functional as active duty personnel and continues to be.

Results: Data supported conclusion that the functional test and isokinetic tests had a fair ($r=40-50$) correlation. Also functional test performance showed statistical improvement between test days (co 24.96 cm) ($p < .001$). Research is currently in process of preparation to be sent to JOSER (Journal of Orthopaedic and Sports Physical Therapy) in hopes that it may be published.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-82-91 Status: Completed

Title: Adaptation to Electrical Stimulation in Torque Generation Capabilities of Three Different Waveforms.

Start date: 30 Aug 91	Estimated completion date:
Principal Investigator: Todd Sander, ENS, SP	Facility: Brooke Army Medical Center, Texas
Department/Service:	Associate Investigator(s): Edward Schrank, LTJG, SP Brent Kelin, ENS, SP
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): To study subject intrasession adaptation to electrical stimulation between first and second trials. Three commonly used waveforms will be used and the intrasession adaptation to each will be compared.

Technical Approach: Subjects will be randomly assigned to one of three groups corresponding to a particular waveform. Each subject will be positioned on all isokinetic dynamometer and set up for quadriceps femoris muscle testing. Maximum voluntary isokinetic torque (MVIT) will be measured. After a rest period, the subject will be electrically stimulated using a neuromuscular electrical stimulation (NMES) machine to obtain a maximum tolerated contraction (MTC) for trial one. After a rest period of 10 minutes, the subject will again be electrically stimulated with the same waveform and MTC for trial 2 will be recorded. The peak of the two trials will then be expressed as a percentage of MVIT and the result for each waveform and each group will be compared.

Progress: All data collection is complete and this project is closed. Results of this project will be published in the Journal of Orthopaedic and Sports Physical Therapy (JOSPT).

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-75 Status: Completed

Title: The Effects of Learning on Performance Gains in Functional Tests for the Knee

Start date:	Estimated completion date:
Principal Investigator: 2LT Jason S. Griffith, PT Student	Facility: Brooke Army Medical Center, Texas
Department/Service: USAMEDD Center and School, FSHTX	Associate Investigator(s): CPT Rebecca Nowlin, SP MAJ John Halle, SP MAJ Mike Kennedy, SP
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 45
 Total number of subjects enrolled to date: 56
 Periodic review date: Review results:

Objective(s): To examine the effects of learning on performance of four functional tests for the knee. If effects are shown, our second purpose is to determine if learning plateaus occur. The tests we will examine are: the one-leg hop for distance (OLHD), the triple hop for distance (TH), the crossover hop for distance (CD) and the one-leg hop for time (OLHT).

Technical Approach: Independent variables in our study will be the three subject groups and time (weekly functional test assessments for six weeks). The dependent variable will be the amplitude of performance measured in units appropriate to the test (i.e., centimeters for the distance tests and seconds for the timed hop).

Progress: Results achieved. Study completed.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-76

Status: Ongoing

Title: The Effects of Pulsed Magnetic Fields on Isokinetic Performance of the Quadriceps Femoris

Start date: Jul 92	Estimated completion date: Mar 93
Principal Investigator: 2LT Shari L. Fox, BSC, USAMEDD Ctr&Sch	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy	Associate Investigator(s): 2LT Brian Boutilier, SP 2LT Julie Johnson, SP
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 20
 Total number of subjects enrolled to date: 20
 Periodic review date: _____ Review results: _____

Objective(s): The purpose of this study is to assess the effects of pulsed magnetic fields (PMFs) on time to peak torque, peak torque, and the number of repetitions to 50% of maximum peak torque of the quadriceps femoris.

Technical Approach: Subjects will consist of 20 healthy male service members between 18 and 40 years of age. Subjects with cardiac pacemakers, cardiac arrhythmias, or metallic implants will be eliminated from the study. Subjects will be screened for previous history of knee or quadriceps muscle pathology and will not be using tobacco products or medication currently.

Progress: Twenty healthy male military service members volunteered to participate in the study. One subject reported a history of meniscal problems and was eliminated from the study. The remaining subjects, ages from 18 to 34 years (Mean=22.68, SD=6.45), reported no history of knee or hip pathology, were nonsmokers, and were currently taking no medication.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-77 Status: Ongoing

Title: Effects of Quadriceps Muscle Length on Hand-Held Dynamometer Torque Measurements

Start date: Jul 92	Estimated completion date: Mar 93
Principal Investigator: 2LT JoAnn Tymeson, SP	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy, USAMEDD Ctr & Sch	Associate Investigator(s): 2LT Barbara Syler, SP 2LT Holly Hammen-Glese
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 44
 Total number of subjects enrolled to date: 44
 Periodic review date: Review results:

Objective(s): To determine the effect of different angles of knee flexion on the isometric quadriceps peak torque values obtained from a hand-held dynamometer (HHD) and isokinetic dynamometer (IKD). If there is an observed difference in HHD and IKD peak torque values, the contributions of strength, height, weight, and gender of the HHD tester will be determined.

Technical Approach: Pilot study will be performed by the investigators to establish the reliability of the method used to assess the upper body strength of the testers. The force transducer of the KINCOM will be set up to simulate the position of the subject's leg during an isometric contraction of the quadriceps muscles.

Progress: Main finding was that no statistical difference between quadriceps muscle peak torque measurements taken with the HHD and IKD was observed at 30 degrees of knee flexion. The clinical significance of this information is that when using the HHD to test strong muscle groups like the quadriceps, reliability and accuracy may be enhanced by testing the muscle at a less than optimal length-tension relationship.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-78 Status: Completed

Title: Effect of Immediate Cold Application on Indicators of Delayed-Onset Muscle Soreness

Start date: Jul 92	Estimated completion date: Mar 93
Principal Investigator: 2LT Shawn J. Scott, SP	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy, USAMEDD Ctr & School	Associate Investigator(s): CPT John M. Stand, SP 2LT Lance C. LeFurge, SP
Key Words: delayed onset muscle soreness, cryotherapy, Talog Pain Rating Scale, eccentric exercise.	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 23
 Total number of subjects enrolled to date: 23
 Periodic review date: _____ Review results: _____

Objective(s): To determine if the immediate application of cold for 30 minutes following eccentric exercise will less the 3 indices of delayed-onset muscle soreness (DOMS): perceived muscular soreness, reduced joint motion and reduced strength.

Technical Approach: Twenty-five active duty male soldiers between the ages of 18 and 35 will be selected for this study. After the performance of an exhaustive bout of eccentric exercise to both arms, participants will receive a cold treatment to one arm while the other arm serves as the control. Pre-exercise measures of elbow joint range of motion and maximal voluntary isometric force will be repeated 48 hours post-exercise and the Talag Pain Rating Scale will be used to assess muscular soreness.

Progress: No progress report was furnished by the principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-79 Status: Ongoing

Title: Comparability of Work Output Measures as Determined by Isokinetic Dynamometry and a Closed Kinetic Chain Exercise

Start date: Jul 92	Estimated completion date: Mar 93
Principal Investigator: ENS Michael D. Rosenthal, SP	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy, USAMEDD Ctr & School	Associate Investigator(s): ENS Lawrence L. Baer, SP 2LT Penny P. Griffith, SP ENS Frederik D. Schmitz, SP
Key Words: Closed kinetic chain exercise , lateral step-up, open kinetic chain exercise, work, isokinetic dynamometry	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 40
Total number of subjects enrolled to date: 40
Periodic review date: Review results:

Objective(s): To determine the magnitude of the relationship between work output measured by a Later Step-Up Test and the work output measured by an Isokinetic Dynamometer test over a given time interval.

Technical Approach: Sixty subjects with no history of knee pathology will be screened by performing one squat to 90 degrees knee flexion, 10 standing toe raises, and 10 one-legged hops, all performed with the extremity to be tested.

Progress: No annual progress was provided by the principal investigator

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-80

Status: Completed

Title: A Comparison of Right and Left Orthodromic Sensory and Motor Neural Conduction Amplitudes of the Median and Ulnar Nerve in Health Adults

Start date:	Estimated completion date:
Principal Investigator: CPT Daniel Rendeiro, SP	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy, USAMEDD Ctr & School	Associate Investigator(s): 2LT David Graves, SP 2LT Jennifer Miller, SP 2LT Tracy Smith, SP
Key Words: electrophysiological testing, SNAP, CMAP, nerve conduction amplitude	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 47
Total number of subjects enrolled to date: 47

Periodic review date: Review results:

Objective(s): To determine the ratio between contralateral sensory and motor nerve evoked amplitudes of the median and ulnar nerves in healthy adults.

Technical Approach: The amplitudes and latencies of the CMAP and the SNAP of median and ulnar nerves will be measured orthodromically at the wrist using standard clinical electrophysiological techniques.

Progress: A ratio was calculated for each subject by dividing the smaller amplitude by the larger, disregarding handedness; thus, ratios were calculated for the median and ulnar CMAP's and the median ulnar SNAP's. Values reported are mean plus-minus standard deviation as a percentage (ratio * 100). Analysis of variance (ANOVA) was performed to determine whether there was a significant effect of gender or handedness on amplitude ratios. Our results provided more precise reference ratio values between contralateral median and ulnar nerve evoked potential amplitudes. These values can be used as a guideline for evaluating and interpreting results of electrodiagnostic testing.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-40 Status: Completed

Title: Short Term High Dose Steroids in Oral and Maxillofacial Surgery

Start date:	Estimated completion date:
Principal Investigator: MAJ Ronald C.D. Butler, DC	Facility: Brooke Army Medical Center
Department/Service: DENTAC/Oral & Maxillofacial Surgery	Associate Investigator(s): LTC Andrew Vorono, DC
Key Words: Pulsed Steroids Serum Cortisol Suppression	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 20
 Total number of subjects enrolled to date: 20
 Periodic review date: Review results:

Objective(s): The purpose of this investigation is to determine the effects of high dose steroids on serum cortisol levels in oral surgery patients.

Technical Approach: Patients who undergo orthognatic preprosthetic, and reconstructive surgery receive a standard course of steroid therapy. They receive 10mg of decadron at beginning of surgery, then 10mg every three hours while they are in surgery. Postoperatively, they will receive 8mg of decadron every six hours for three doses then one IM injection of 80mg of Depo-Medrol six hours after the last dose of decadron. Patients are normally followed up on a weekly basis for four weeks then monthly up to about six months. Patients serum cortisol level will be check at the time of admission, immediately post-op on the day of surgery, post-op day three which would correspond to maximum suppression, post of day four which is after the delayed release steroid, then on a weekly basis until the serum cortisol level returns to baseline.

Progress: The project was completed. The results showed no long-term suppression > 7 days with either dosing regime of IV decadron. The study was submitted to the Journal of Oral and Maxillofacial Surgery and accepted for publication.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-87-91 Status: Terminated

Department/Service:
Department of Emergency Medicine

Associate Investigator(s):
Robert A. Liebold, CPT, MC
Donald M. Yealy, MD

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____

Total number of subjects enrolled to date: _____

Periodic review date: _____ Review results: _____

Objective(s): To determine the relative efficacy of prochlorperazine, metoclopramide, and normal saline placebo in the emergency department treatment of migraine headache.

Technical Approach: After obtaining informed consent, patients will be asked to grade their headache, sedation, and degree of nausea on a visual analog scale. Patients will be randomized to receive either metoclopramide, prochlorperazine, or placebo by IV. After 30 minutes patients will again grade their headache, sedation and degree of nausea. If there is a 50% or greater reduction of pain, they will be discharged. If their headache is not sufficiently relieved after 30 minutes, the attending physician will be consulted and further therapy administered. If the patient first received a placebo, he will then be randomized to one of the study drugs.

Progress: No report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-7 Status: Ongoing

Title: Comparison of Cimetidine, Ranitidine, and Diphenhydramine in the Treatment of Acute Urticaria Over a Seventy-Two Hour Period

Start date: 1 Feb 92	Estimated completion date: 1 Feb 94
Principal Investigator: CPT Anthony Ferrara, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine, DAH, Ft Hood, TX	Associate Investigator(s):
Key Words: Cimetidine Urticaria Ranitidine Diphenhydramine	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4
Total number of subjects enrolled to date: 18

Periodic review date: _____ Review results: _____

Objective(s): To determine the effectiveness of cimetidine, ranitidine and diphenhydramine in the treatment of acute urticaria during the immediate ER follow-up period.

Technical Approach: Subjects in this study will include 120 male and female patients between the ages of 16 and 55 presenting to the Emergency Room at Darnall Army Community Hospital with signs and symptoms consistent with acute urticaria of less than 24 hour duration. Presenting symptoms should include itching, swelling, and rash.

Progress: No progress report provided by principal investigator.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-31 Status: Terminated

Title: An evaluation of Clinical Criteria for Predicting Serious Bacterial Infections in Febrile Infants Two Months of Age or Less

Start date:	Estimated completion date:
Principal Investigator: CPT Kenneth D. Locke, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine, DAH, Ft Hood, TX	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): 1) To test the predictive value of a predetermined set of clinical and laboratory findings along with subjective "impression of sepsis" for predicting serious bacterial illness in febrile infants two months of age or less in a community hospital emergency department. 2) To compare the use of these criteria and the subjective impression by three groups of physicians: emergency medicine residents, emergency medicine staff physicians, and staff pediatricians.

Technical Approach: All febrile ($T > 100.3R$) infants 8 weeks of age or less who present to the Emergency Department of Darnall Army Community Hospital will be eligible for the study. Patients will be excluded if they have had a previous hospitalization or were delivered prematurely.

Progress: Difficulty in enrolling patients and having Pediatrics cooperation.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-46 Status: Ongoing

Title: Dental Liquid Ration Test (Natick Study)

Start date: 1 May 93	Estimated completion date: 1 May 94
Principal Investigator: CPT Carol J. Baker, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Nutrition Care, DAH, Ft Hood, TX	Associate Investigator(s):
Key Words: Liquid Ration Test	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
 Total number of subjects enrolled to date: _____
 Periodic review date: _____ Review results: _____

Objective(s): Estimates of food and fluid consumption will be collected and subjects' nutrient intakes will be compared with the Military Recommended Dietary Allowances. Nutrient intakes of non-military personnel will be compared to the Recommended Dietary Allowances.

Technical Approach: Subjects will consist of approximately 150 patients 18 years old or above (300 patient equivalent days) in military and veterans hospitals and, in addition, a minimum of 25 geriatric and 25 cancer patients (100 patient equivalent days) who would ordinarily be consuming a liquid and/or pureed diet during their hospital stay.

Progress: Study will not start until 1 May 93.

Detail Summary Sheet

Date: 4 Feb 93

Protocol Number: C-92-62

Status: Completed

Title: Effectiveness of Splinting for Carpal Tunnel Syndrome During Pregnancy

Start date: Nov 89

Estimated completion date: May 92

Principal Investigator:
MAJ Robbie Courts, SP

Facility:
Darnall Army Community Hospital

Department/Service:
Occupational Therapy

Associate Investigator(s):
SGT Kelly Small, OTA

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____

Total number of subjects enrolled to date: _____

Periodic review date: _____ Review results: _____

Objective(s): To evaluate the effectiveness of an individually fabricated (polyform) volar wrist splint in decreasing the subjective and objective symptoms of Carpal Tunnel Syndrome (CTS) during pregnancy.

Technical Approach: Eight subjective symptoms (tingling, numbness, pain, weakness, wakes you up, drops things, swelling, and stiffness) were rated by the patients at each visit on a scale of 0/"none" to 5/"constant". Objective symptoms of grip and pinch (2-point, 3-jaw, and lateral) were also measured. Measurements were taken at the initial referral, at one week follow-up after splinting, and four weeks postpartum. Treatment included splinting and patient education on CTS and the importance of wrist positioning during sleep and activities.

Progress: Data collection was completed May 92. Preliminary results indicate: 1) There was an average increase in grip and three types of pinch ($p < .0001$) in 134 involved hands one week after splinting; 2) There was a decrease in all eight subjectively rated symptoms one week after splinting ($p < .0001$); 3) At one month postpartum, the eight subjective symptoms were rated as absent in 86% to 94% of the involved hands (77 to 119 hands for each symptom).

Technical Approach: Improvement was evaluated by comparing change in subjective symptoms and grip/pinch measurements from the initial visit to the

C-92-62 (continued)

first follow-up visit. Postpartum measurements were compared to established norms for return to normal, and absence of subjective symptoms was assessed. A control group of women who had not had any problems with their hands during pregnancy was added to compare grip/pinch measurements at four weeks postpartum, considering normal leisure and work use of hands are frequently altered during pregnancy and established norms may not be relevant for this group.

Progress: 3) At one month postpartum, the hands with CTS symptoms during pregnancy had not regained normal strength; 5) At one month postpartum, the women with no hand problems during pregnancy did have normal grip/pinch measurements.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-71 Status: Ongoing

Title: Urinary Toxicologic Screening After Dermal Exposure to Cocaine

Start date: 15 Aug 92	Estimated completion date:
Principal Investigator: CPT Laurel Kietzman, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine, DAH, Ft Hood, TX	Associate Investigator(s): Brian Baxter, MD Carolyn Tiffany, MD Trudi McGrath, MD Jay Still, MS
Key Words: Cocaine Tox Screen	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 39

Total number of subjects enrolled to date: 39

Periodic review date: Review results:

Objective(s): To determine whether dermal exposure to an 11.8% cocaine solution followed by cleansing with alcohol and IV angiocath insertion, produces detectable urinary levels of benzoylecgonine.

Technical Approach: Project design is a prospective, quantitative data collection which will involved 40 adult volunteers between ages 18-65.

Progress: Data were analyzed for differences in cocaine levels between collection times using one-way ANOVA with paired comparisons using Wilcoxon Signed Rank Test. If ANOVA reached significance; $p = 0.05$ was significant. No subjects were found to be positive by National Institute of Drug Abuse (NIDA) Standards. There were detectable levels of cocaine or cocaine metabolites found in urine samples at 24 hours, 48 hours and 7 days from TAC application. This would suggest that cocaine 11.9% in TAC solution would not produce false positive screening tests for cocaine.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-72 Status: Completed

Title: Use of TAC as Topical Anesthesia for Angiocath Placement

Start date: 15 Aug 92	Estimated completion date:
Principal Investigator: CPT Trudi K. McGrath, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine, DAH, Ft Hood, TX	Associate Investigator(s): CPT Brian Baxter, MC CPT Carolyn Tiffany, MC CPT Laurel Kietzman, MC
Key Words: TAC	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 39
 Total number of subjects enrolled to date: 39
 Periodic review date: Review results:

Objective(s): To determine the effectiveness of percutaneous TAC as a topical anesthetic for decreasing the pain caused by IV angiocatheter placement.

Technical Approach: Project design is a prospective, randomized, double-blind, placebo-controlled trial to evaluate the effectiveness of TAC as a topical anesthetic on intact skin for decreasing the pain of IV angiocath placement.

Progress: Differences in pain scores between groups (TAC vs placebo) were measured with the Mann-Whitney-U Test; $p = 0.05$ was considered significant. Our trial had a power of 90% to detect a difference 2.5cm on the VAS between groups. Median pain scores did not differ significantly between groups (2-tailed $p = 0.2$). Despite the effectiveness of TAC's anesthetic properties in open wounds, our study suggests that TAC has no anesthetic effect on intact skin.

Detail Summary Sheet

Date: 4 Feb 93 Protocol Number: C-92-87 Status: Ongoing

Title: Comparison of Intramuscular Meperidine and Chlorpromazine, With and Without Promethazine for Pediatric Sedation

Start date: 1 Oct 92	Estimated completion date: 1 Oct 93
Principal Investigator: CPT William D. Rodriguez, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine, DAH, Ft Hood, TX	Associate Investigator(s): MAJ Daniel J. Dire, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 14
 Total number of subjects enrolled to date: 14
 Periodic review date: _____ Review results: _____

Objective(s): To determine if there is a significant difference in the efficacy of sedation and frequency of complications after intramuscular meperidine and chlorpromazine, with and without promethazine (MC vs MPC).

Technical Approach: Pediatric ED patients will be preselected upon their arrival to the ED based on a set criteria for entry into study. Patients entering the study will be greater than 1 year of age and less than 16 years of age having one or more of indications outlined in study.

Progress: Total of 14 patients enrolled to date. No adverse side effects.

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